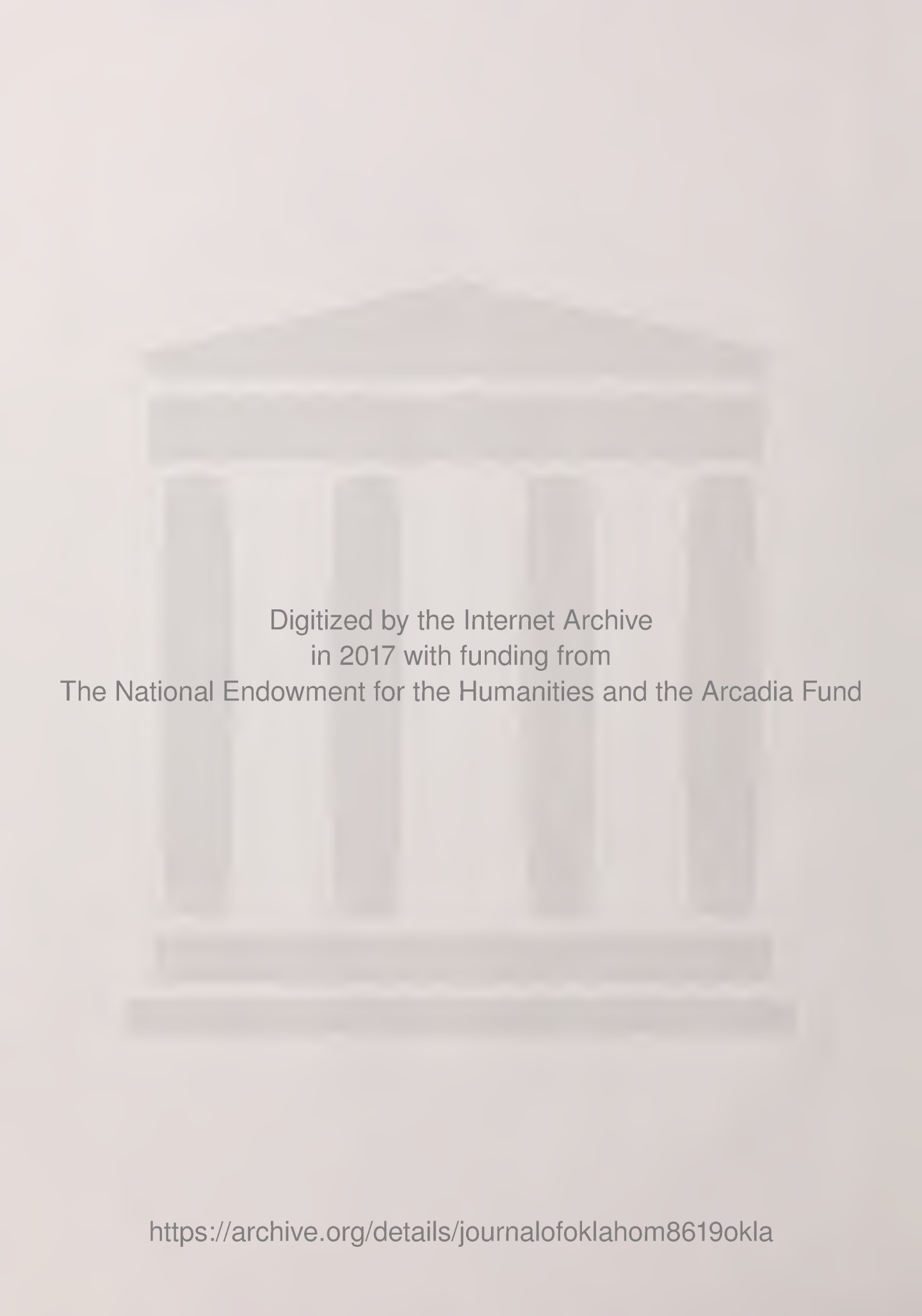
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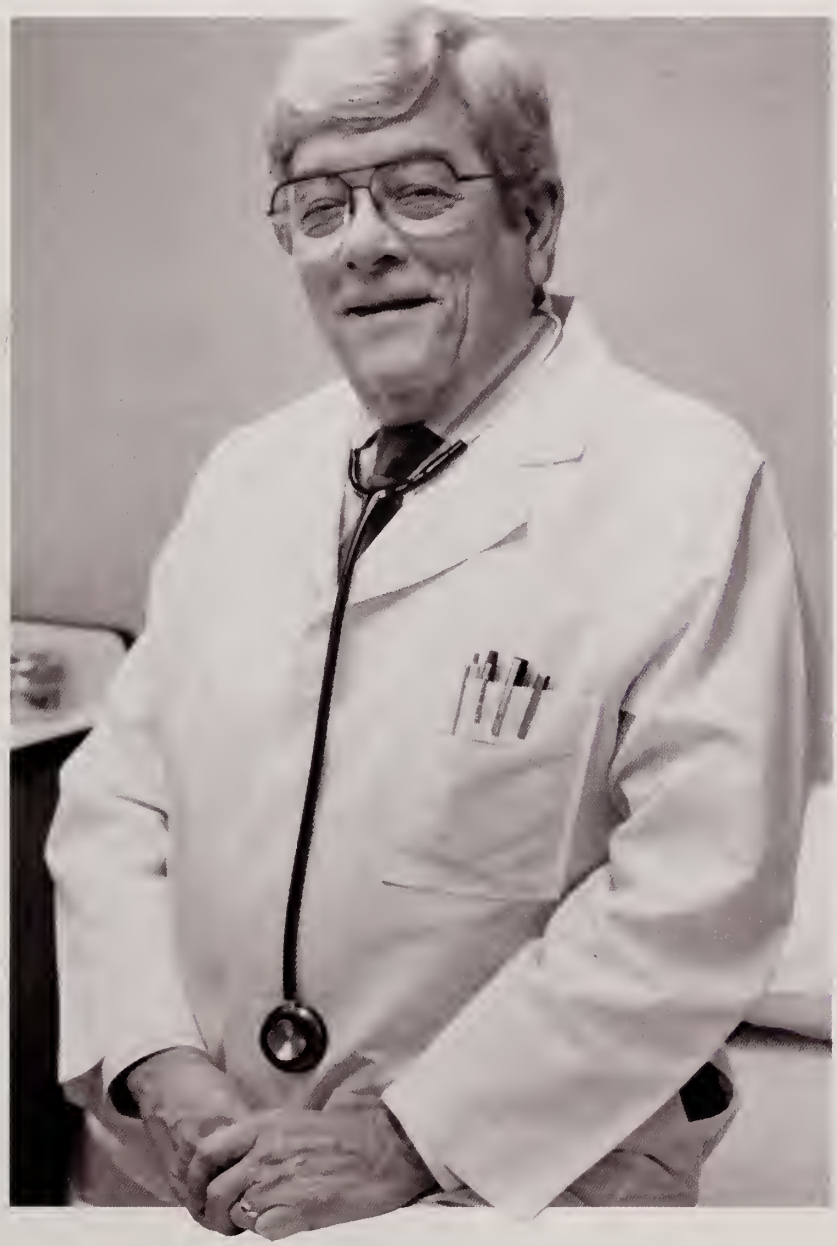
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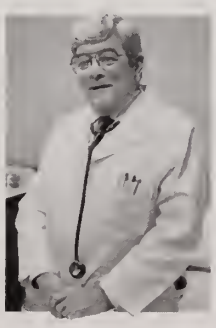
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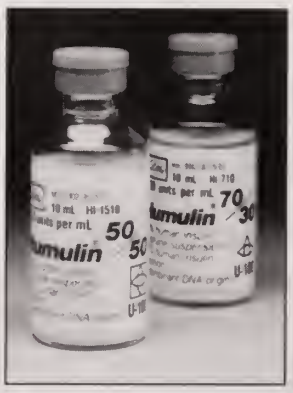
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EDITORIAL

Ray V. McIntyre, MD

On Cost and Value

For years, the "high cost" of medical and hospital care in the United States has been increasingly criticized. The recent national political tides were affected by the public perception that medical costs are unduly high. Unfavorable comparisons to other, and dissimilar, nations are frequent in these political criticisms.

But when we look behind the smoke and thunder of these attacks, we find that most are staged by cohorts engaged in a propaganda war to further a political result, or to market an insurance program, or perhaps to sell an administrative process for a future financial crisis. Never do we hear a logical quantitative analysis of the current factors included in medical prices.

Objectively, what has brought medical costs to their present level?

Inflation is a factor. Forty years ago, a brief office call in this area cost three dollars, and we are now "allowed" twenty-one dollars for the same service—a seven-fold increase. Forty years ago, a first class postage stamp cost three cents, and it now costs twenty-nine cents and will soon be thirty—a ten-fold increase. A postage stamp and a brief office call both represent a basic economic unit of labor intensive service, but we take note that the letter merely moves from point A to point B, just as it did forty years ago. The twenty-one dollar office call, on the other hand, buys access to a vastly expanded body of medical knowledge and treatment efficacy that is at least 1000% more effective than forty years ago. While the cost of the government postal service has inflated ten times, without any increase in value, the value of medical service has increased immeasurably with only a seven-fold increase in cost.

Thus we can see that inflation affects the overall price of many things, but in medicine, technical advances and improvements have increased the *value* of medical care much more than the increase of the *cost* of medical care. The medical scientists have advanced the value of medical care much farther than they have increased costs.

Everywhere, the meal of turnip greens costs less than the meal of fatted calf with trimmings, but no one considers the greens to be a better buy. Cost is not the same as value. No one wants to return to the less costly and less effective medicine of forty years ago.

In addition to inflation and technical improvements, the costs of a medical practice as a business have burgeoned as mandated administrative, licensing, and insurance costs have quadrupled since Medicare enactment. A maze of government regulations has become medicine's heaviest financial burden.

As a society let us recognize that modern medical care is one of the greatest commodities in this world that can be bought with money, and if some, or many, or few, of our citizens cannot now buy this great value, let us, as a society, improve the cash flow of those dispossessed citizens. Let us be cost effective by eliminating the overburden of government regulation and administration, but preserve the modern scientific advances and the scientific autonomy of the physician. Our society really does not want *cheaper* medical care; our society wants *efficient* medical care available to all citizens.

Let us petition Congress to change the US tax structure so that the individual citizen's medical insurance premiums and most medical expenses become income tax deductions. Let us discontinue the big business expense deduction of medical insurance premiums, and then those premium dollars would flow into increased salaries. America would then become a nation full of cost efficient health care buyers.

Ray V. McIntyre, M.D.

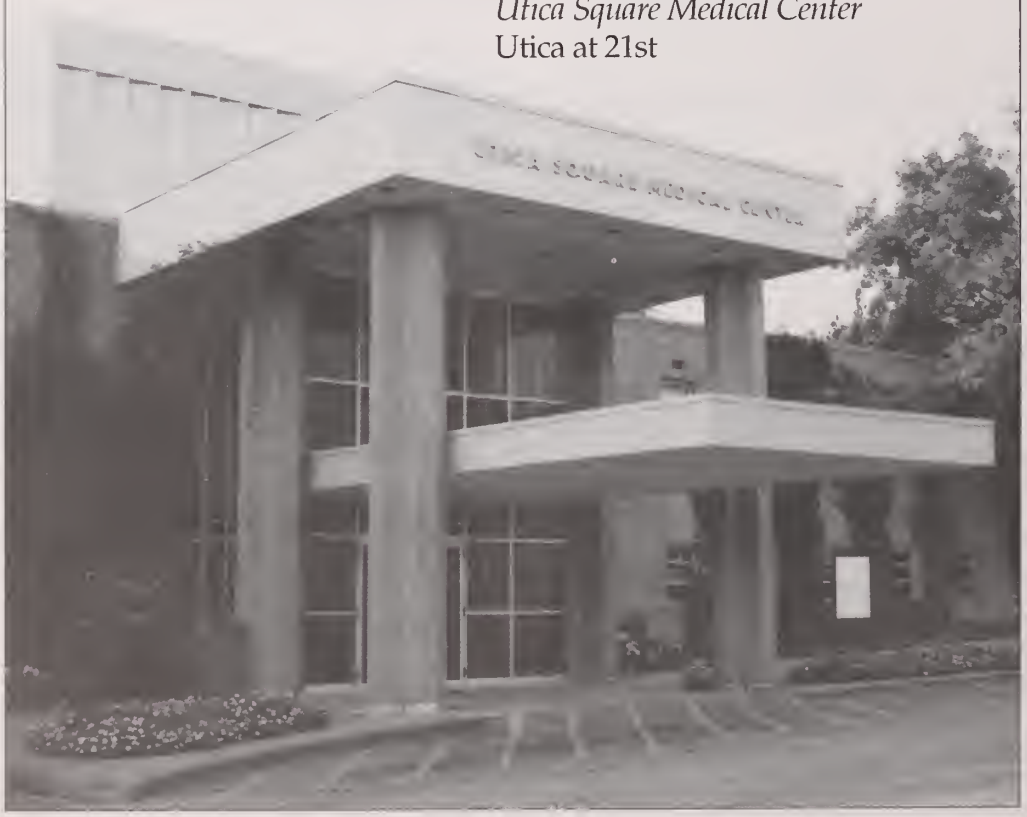
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PRESIDENT'S PAGE

James D. Funnell, MD

The AMA Interim Meeting



We came, we saw, we did not conquer.

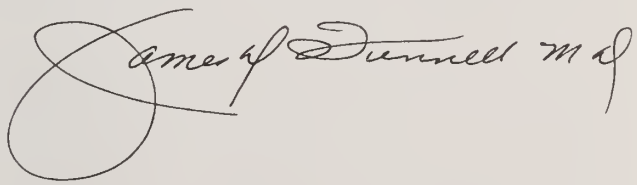
Members of your Oklahoma delegation to the American Medical Association met in Nashville, Tenn., with representatives of the American Medical Association during the AMA Interim Meeting last month. We had an opportunity, as a delegation and as a medical association, to review numerous new proposals that may to come down from Washington after President-elect Clinton takes office.

Medical legislation proposed by Mr. Clinton during his campaign contains elements of the AMA's Health Access America plan. However, he will also look at numerous proposals that other states are trying at this very moment as pilot projects.

Members of your delegation met with AMA President John L. Clowe, MD, board members, and Executive Vice President James S. Todd, MD, to discuss proposed changes in legislation. I can tell you as your president that most of the things we see on the horizon will not be met with enthusiasm by physicians, nor will they be good for American medicine. We examined global fees, managed competition, and other euphemisms, which, like President Roosevelt's New Deal, sound good, but tell you nothing.

Your delegation also met with members of the Arizona delegation to discuss the Arizona Health Care Cost Containment System (AHCCCS), a Medicaid managed care program. The OSMA will continue to meet with these and other Arizona physicians since it appears Oklahoma's troubled and underfunded Medicaid system is headed toward a managed care program.

The main mesage I want to bring to you from the AMA and the Organization of State Medical Association Presidents meeting is how lucky we are to be practicing medicine in the state of Oklahoma where, despite many, many problems, we face a situation not nearly as difficult as that in other states.



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SCIENTIFIC

Symposium on Antimicrobial Therapy
IV. The Cephalosporins

Ronald A. Greenfield, MD

This is the fourth in Dr. Greenfield's series of articles on antimicrobial therapy.

The cephalosporins have a unique notoriety among antimicrobial agents. They are very commonly used, despite the fact that they are recommended as a first choice for the treatment of very few infectious diseases. They are among the most frequently misused therapeutic agents. The family has proliferated dramatically in the past decade, and this proliferation will likely continue in the next decade. Physicians have been bombarded with sales promotions about these drugs, with emphasis often on minor differences between various agents, leading to a state called "cephalosporin confusion."

A structured review of the cephalosporin antibiotics will be presented here. A classification of the over 20 available cephalosporins is presented in Table 1. Although initially a marketing ploy, most physicians are familiar with the discussion of cephalosporin generations, and if used to denote spectrum of antimicrobial activity, this initial classification remains useful. It is *not* necessary that physicians know the details of antimicrobial activity, pharmacokinetics, pharmacodynamics, toxicity, and clinical indications for the use of all 20+ of these drugs. Rather, these agents can be sorted into about half a dozen groups, and a role assigned to an agent from each of these groups. That is our task here.

From the Infectious Diseases Section, Department of Medicine, University of Oklahoma Health Sciences Center, and Medical Service, Department of Veterans Affairs Medical Center, Oklahoma City, Oklahoma. Because the author is an employee of the federal government, this article is specifically excluded from the JOURNAL's copyright.

Direct correspondence to Ronald A. Greenfield, MD, Infectious Diseases Section (111/c), 921 Northeast 13th Street, Oklahoma City, OK 73104.

First Generation Parenteral Cephalosporins

The cephalosporins were initially developed to meet the challenge of staphylococcal resistance to penicillin. Agents were sought which would have activity against streptococci and staphylococci: the result is the first generation cephalosporins. There are now three first generation cephalosporins available for parenteral administration: cephradine, cephapirin, and cefazolin. The antimicrobial activity of these three can be considered identical. There are clinically important pharmacokinetic differences between these three, and in view of these and combined with cost factors, cefazolin is the first generation parenteral cephalosporin of choice. The others need be considered no further. It does become important to know the usefulness, limitations, and correct usage of cefazolin.

The in vitro antimicrobial spectrum of activity of cefazolin includes *Staphylococcus aureus* and coagulase-negative staphylococci (*Staphylococcus epidermidis),* including strains resistant to penicillin and sensitive to methicillin. It can not be overemphasized that methicillin-resistant staphylococci are resistant as well to *all* cephalosporins; even if in vitro susceptibility is demonstrated, there is no in vivo efficacy.[1] It is also to be noted that treatment of staphylococcal endocarditis with cefazolin has too frequently been *un*successful. Cefazolin is also active against most streptococci. It is important to emphasize that en-

Table 1. A Classification of the Cephalosporins

Class and Generic Name	Common Trade Names*
First Generation Cephalosporins	
For parenteral administration	
cephradine	Anspor, Velosef
cephapirin	Cefadyl
cefazolin	Kefzol, Ancef, others
For oral administration	
cephalexin	Keflex, others
cephradine	Veolsef, others
cefadroxil	Duricef, Ultracef
Second Generation Cephalosporins	
For parenteral administration	
Group I	
cefamandole	Mandol
cefuroxime	Zinacef, Kefurox
cefonicid	Monocid
ceforanide	Precef
Group II - cephamycins	
cefoxitin	Mefoxin
cefotetan	Cefotan
cefmetazole	Zefazone
For oral administration	
cefaclor	Ceclor
cefuroxime axetil	Ceftin
cefprozil	Cefzil
Third Generation Cephalosporins	
For parenteral administration	
aminothiazolyl-methoxyimino-cephalosporins	
cefotaxime	Claforan
ceftizoxime	Cefizox
ceftriaxone	Rocephin
cefoperazone	Cefobid
ceftazidime	Fortaz, others
For oral administration	
cefixime	Suprax

*Inclusion or omission of particular trade products does not imply endorsement or lack of endorsement.

terococci are resistant to *all* cephalosporins. Among aerobic Gram-negative bacteria, cefazolin is active against some *Escherichia coli, Proteus mirabilis,* and *Klebsiella pneumoniae,* and rarely other organisms, as shown in Table 2. Although active against some anaerobic Gram-positive cocci, the anaerobic activity of cefazolin is clearly inferior to that of penicillin G or ampicillin.

Some important aspects of cefazolin pharmacokinetics are as follows.[2] Peak serum levels after a 1 gm intravenous infusion are 50-75 µg/ml (for reference, sensitive *Staphylococcus aureus* are inhibited by 1 to 2 µg/ml) and the serum half-life is 90 to 120 minutes. Tissue penetration is excellent except for the central nervous system (CNS) and cerebrospinal fluid (CSF). The overwhelming majority of patients can be treated with 1 gm q8h or less. For skin and skin structure infections, a dose of 0.5 gm q8h is adequate. For uncomplicated urinary tract infections, 1 gm q12h is appropriate. Doses of 6-12 gm a day may be required for treatment of osteomyelitis, however. For surgical prophylaxis, the critical dose is 1 gm 1 hour preoperatively. Multiple studies emphasize the importance of adequate tissue levels at the time the incision is made. For certain surgical procedures, two additional doses at 6 to 8 hour intervals may be appropriate.

Reasonable clinical uses of cefazolin can be summarized as follows: (1) infections (other than endocarditis) due to *Staphylococcus aureus* in hospitals with a low incidence of methicillin resistant *S. aureus* infections, or after in vitro documentation of methicillin susceptibility, (2) infections that may be either staphylococcal or streptococcal, (3) infections with *S. epidermidis* proven susceptible to methicillin in vitro, (4) streptococcal but not enterococcal infections, (5) infections due to *E. coli, P. mirabilis,* and *K. pneumoniae* after proven in vitro susceptibility, (6) substitution for penicillins in patients with a history of non-immediate hypersensitivity reactions to penicillins, and (7) surgical prophylaxis against staphylococcal and streptococcal wound infections in cardiovascular, orthopedic, biliary, pelvic, and intra-abdominal surgery.

First Generation Oral Cephalosporins

Of all antimicrobials, this is likely the group most widely overused and improperly used. The spectrum of activity of these agents is similar to that of the injectable first generation cephalosporins. There are three agents in this group: cephalexin, cephradine, and cefadroxil. Cefadroxil has a somewhat longer half-life than the others; however, I do not believe this comparatively minor pharmacokinetic difference of dubious clinical importance overcomes the price disadvantage of this agent. Cephalexin and cephradine are virtually identical; a choice between these two can be made solely on local cost factors.

Much of the overuse of these agents is directed at staphylococcal infections. These are *poor* anti-staphylococcal antibiotics. For example, the median minimum inhibitory concentration for *S. aureus* by cephalexin is 3.4 µg/ml. The peak serum level after a 500 mg oral dose (and only half this dose is often given) is 20 µg/ml; the serum half-life is about one hour. Thus serum levels exceed the inhibitory concentration for about three hours. Therefore these

Table 2. Summary Activity of Selected Cephalosporins Against Representative Microorganisms*

Drug	Gram-Positive Cocci		Gram-Negative Bacilli			Anaerobes		
	S. aureus	*Strep*	*E. coli, P. mirabilis Klebsiella*	*Enterobacter, Serratia,* others	*P. aeruginosa*	*B. frag.*	Others	*Haemophilus influenzae*
Cefazolin	4	4	3	—	—	—	2	2
Cefuroxime	3	4	4	2	—	—	3	3
Cefoxitin	2	2	4	2	—	2	3	2
Cefotaxime	3	3	4	3	—	2	3	4
Ceftizoxime	2	3	4	3	—	2	3	4
Ceftriaxone	2	3	4	3	—	—	3	4
Ceftazidime	—	—	4	4	4	—	2	4

*Adapted from reference 5.

drugs are poor substitutes for semisynthetic penicillinase-resistant penicillins (cloxacillin or dicloxacillin) for oral therapy of staphylococcal infections.

In fact, the usefulness of these agents is quite limited. One indication would be minor infections (such as uncomplicated urinary tract infections) due to aerobic Gram-negative bacilli proven susceptible in vitro to first generation cephalosporins but resistant to ampicillin and amoxicillin.

Second Generation Parenteral Cephalosporins

The second generation cephalosporins were developed to extend the spectrum of activity of cephalosporins to encompass more aerobic Gram-negative bacilli. In addition to the gains there have been some losses. This has been likened to a person in bed covered with a blanket; as the blanket is raised to cover his/her head, his/her feet stick out. The gains of the second generation cephalosporins over the first generation agents are: (1) expanded spectrum against aerobic Gram-negative bacilli, (2) enhanced activity against β-lactamase positive *Haemophilus influenzae* (activity of ceforanide and the cephamycins is marginal), (3) activity against anaerobic Gram-negative bacilli, predominantly *Bacteroides fragilis* (the cephamycins), and (4) prolonged half-life (ceforanide and cefonicid). The drawbacks of the second generation agents compared to first generation agents are: (1) loss of activity against Gram-positive bacteria (less loss with cefamandole and cefuroxime than the others), (2) potential for development of resistance during therapy,[3] (3) additional toxicities, and (4) expense.

The seven second generation cephalosporins available in the US are divided into two groups (Table 1). The first group consists of cefamandole, cefuroxime, cefonicid, and ceforanide. There are important differences in the in vitro antimicrobial spectrum within this group. Whereas cefamandole and cefuroxime have reasonable activity against methicillin-susceptible *S. aureus,* cefonicid and ceforanide should not be used for infections due to Gram-positive organisms. These agents are grouped together because of their similar in vitro activity against aerobic Gram-negative bacilli. All have reasonable activity against some such organisms, primarily *E. coli, P. mirabilis* and *vulgaris, K. pneumoniae,* and *Enterobacter aerogenes.* Representative activity of cefuroxime is shown in Table 2 and Table 3. As can be seen, this activity is intermediate between first and third generation cephalosporins.

Pharmacokinetic differences within this group are also clinically significant. When compared at pharmacokinetically equivalent doses, cefuroxime 1.5 gm q8h is less expensive than cefamandole 2 gm q4-6h. Therefore we can eliminate cefamandole from further discussion. The proposed advantages for the other agents in this group are even longer serum half-lives, circa 4.5 hours for cefonicid and 3.0 hours for ceforanide. Although potentially useful for outpatient parenteral therapy of a limited number of moderate Gram-negative bacillary infections, the usefulness of these two agents is modest, and they will not be discussed further. That leaves cefuroxime as the sole member of this group for discussion.

The clinical indications for use of cefuroxime are somewhat limited but important. Its activity against *S. aureus,* streptococci, and *H. influenzae* makes this drug useful in severe upper and lower respiratory tract infections, particularly in postinfluenzal pneu-

Table 3. Sensitivity of Aerobic Gram-Negative Bacilli to Selected Cephalosporins*
(% strains susceptible to achievable concentrations)

Bacteria	# Tested	Cefazolin	Cefuroxime	Cefotaxime
Enterobacteriaceae				
Escherichia coli	4,222	96	97	100
Enterbacter aerogenes	342	11	74	85
E. cloacae	556	4	52	83
Serratia marcescens	263	0	0	98
Klebsiella pneumoniae	1,057	97	93	100
K. oxytoca	350	63	90	99
Morganella morganii	175	0	3	97
Proteus mirabilis	544	96	98	100
P. vulgaris	52	6	6	100
Citrobacter diversus	105	96	91	99
C. freundii	277	7	71	85
Pseudomonas aeruginosa	1,449	0	1	23
Xanthomonas maltophilia	280	0	0	6
*Acinetobacter c.** Iwoffi*	90	17	73	89
*A. c.** anitratus*	134	1	8	46

*Adapted from reference 5.
**c.=*calcoaceticus*

monia, where these are the dominant pathogens. Cefuroxime is an excellent choice for treatment of invasive *H. influenzae* infections until ampicillin susceptibility is known, or if β-lactamase production is documented. Cefuroxime is the only second generation cephalosporin that achieves effective CSF concentrations; it is probably the treatment of choice for susceptible *S. aureus* meningitis in patients with non-immediate hypersensitivity to penicillins. Some aerobic Gram-negative bacillary infections can be treated with cefuroxime, after documented in vitro susceptibility, with greater cost effectiveness than with the use of a third generation cephalosporin.

A new toxicity was introduced to the cephalosporin family, beginning in this generation. Cephalosporins containing the methylthiotetrazole (MTT) side chain include cefamandole, cefotetan, cefmetazole, and cefoperazone. Ceftriaxone bears a related structure. It has been shown that the MTT side chain or its metabolites interferes with synthesis of the vitamin K–dependent clotting factors.[4] This can result in a prolonged prothrombin time and clinically significant bleeding. Administration of vitamin K prophylactically to patients who have poor intake of vitamin K and are treated with one of these agents is warranted. The MTT side chain has also been associated with a disulfiram-like (Antabuse)-like) effect after ingestion of ethanol.

The second group of second generation parenteral cephalosporins shown in Table 1, cefoxitin, cefotetan, and cefmetazole, are technically cephamycins, due to a 7-α-methoxy substitution on the cephalosporin nucleus. The activity of this group against anaerobic bacteria, including *Bacteroides fragilis,* gives it a unique and useful position among cephalosporins. None of these drugs, however, is the agent of choice for a major substantiated anaerobic infection.[5] The antimicrobial spectrum of these agents is represented by cefoxitin in Table 3. While differences exist, I give the advantage to cefotetan on the basis of pharmacokinetics and cost. This drug is useful in prophylaxis in ob/gyn surgery[6] and is useful in treatment of some infections of the female pelvis. Similarly, parenterally administered cefoxitin has been useful in addition to topical prophylaxis when administered before elective colorectal surgery.[7] Although cephamycins have been used as single agents for intraabdominal infection, they lack enterococcal activity, and patients with a known hospital-acquired infection or who have recently received antimicrobial therapy require additional therapy for aerobic Gram-negative bacilli. Cefotetan is most frequently dosed as 2 gm q12h for treatment of infection. A single 2 gm dose is adequate for surgical prophylaxis.

Second Generation Oral Cephalosporins

There are three agents in this category (Table 1), although the β-lactamase stability of cefaclor is actually not that of a second generation cephalosporin. Therefore the advantage in this group belongs to cefuroxime axetil and cefprozil. Cefuroxime axetil is an ester of cefuroxime that is quickly deesterified: the antimicrobial activity is that of cefuroxime, discussed above. Cefuroxime axetil or cefprozil is useful for less severe infections of the same types for which parenteral cefuroxime would be used, and for completion of a course of therapy initially administered parenterally. The main indication for cefuroxime axetil or cefprozil is oral treatment of infections due to β-lactamase producing *H. influenzae.* The cost advantage between these two may belong to cefprozil. Cost comparisons for these agents should be made to amoxicillin-clavulanic acid, the new macrolides, and the fluoroquinolones.

Third Generation Parenteral Cephalosporins

There are now five agents in this group: cefotaxime, ceftizoxime, ceftriaxone, cefoperazone, and ceftazidime. Three of these are chemically very similar and have very similar antimicrobial spectra of activity: these are the aminothiazolyl-methoximino-cephalosporins: cefotaxime, ceftizoxime, and ceftriaxone. The third generation cephalosporins were developed for improved stability against the β-lactamases of aerobic Gram-negative bacilli and thus enhanced activity against these organisms. Indeed these drugs have activity against the aerobic Gram-negative bacilli that begins to approach that of the "gold standard" in this regard, the aminoglycosides.

Let's discuss cefoperazone first. This agent does not have the stability to β-lactamases of the other third generation cephalosporins, and therefore its in vitro activity is inferior to the others against Gram-negative aerobic bacilli.[8] However, its in vivo efficacy, at a dose of 2 gm intravenously q12h has been amply documented for serious Gram-negative bacillary infections,[9] and this dosage is currently the least expensive third generation cephalosporin regimen. Cefoperazone should *not* be used for meningitis because efficacious CSF concentrations are not reliably achieved. This dosage regimen is *not* effective against infections with *Pseudomonas aeruginosa;* although higher dosages have achieved some success in this regard, these are no longer cost effective. The predominant hepatic excretion of cefoperazone (in microbiologically active form) affords an advantage for use of this agent in biliary tract infections.[10]

One should know that cephalexin is massively overused, and really now not all that useful an agent.

There are differences among the antimicrobial spectrum of the three aminothiazolyl-methoximino-cephalosporins, but the similarities far outweigh the differences. These have the broadest spectrum of in vitro activity against aerobic Gram-negative bacilli, other than *P. aeruginosa,* of the cephalosporin family. Highlights of the antimicrobial spectrum of the agents are presented in Table 2 and Table 3. There are also clinically significant pharmacokinetic differences among these three agents. Much of the marketing strategy of these agents in the past several years is based on decisions comparing equivalent dosing regimens. Perhaps the simplest way to view this is to compare maximum daily doses, ie, the doses that would be used for treatment of Gram-negative bacillary meningitis: cefotaxime 2 gm q4h, ceftizoxime 2 gm q4h, and ceftriaxone 2 gm q12h. For moderately severe infections, this dose could be reduced by half: cefotaxime and ceftizoxime 2 gm q8h, and ceftriaxone either 2 gm q24h or 1 gm q12h. Based on these dosing schedules, it is reasonable to pick one of these agents. Pricing varies locally and over time, so I can not make a global recommendation in this regard. Additionally, the patent expires on cefotaxime within the next two years, and this will likely begin to affect the pricing of all agents in this group soon.

What, then, are the appropriate clinical uses of the third generation cephalosporins in this group? One of these drugs is clearly the therapy of choice for Gram-negative bacillary meningitis, and clearly has improved efficacy in this situation over prior therapeutic alternatives.[11] Remarkably, that is the sole indication for a third generation cephalosporin as a drug of choice for hospitalized patients. However, these drugs have demonstrated usefulness in a variety of settings. The time to consider use of these agents is for nosocomial (hospital-acquired) infections which likely involve multiply drug-resistant Gram-negative bacilli, preferably after documentation of in vitro susceptibility. In these situations, these agents can be used in the place of aminoglycosides, thus avoiding the nephrotoxicity and ototoxicity of that class of agents. Favorable response rates of 80% to 90% have been demonstrated for treatment of pneumonias, bacteremias, urinary tract infections, intraabdominal infections (as part of a regimen including more definitive therapy for anaerobes), and infections of the skin and supporting structures, as reviewed.[1] Additionally, ceftriaxone has become a therapy of choice for urethral, anorectal, and oropharyngeal gonorrhea,[12] and for patients with late manifestations of Lyme disease.[13]

One additional toxicity requires note. For reasons not fully explained, high dose ceftriaxone therapy is associated with biliary pseudolithiasis.[14]

The remaining third generation parenteral cephalosporin is ceftazidime. The principal virtue of ceftazidime is that it is the most active of all available cephalosporins against *P. aeruginosa.* Its expense, even relative to other third generation cephalosporins, restricts its usefulness to situations of documented or highly suspect *P. aeruginosa* infections in

patients who cannot be treated with an extended spectrum penicillin. It tends to be dosed low often: for serious *P. aeruginosa* infections (and again this is the only time this drug should be used) the dosage should be 2 gm q8h. Serious *P. aeruginosa* infections require synergistic therapy with an aminoglycoside in addition to ceftazidime. Despite some initial enthusiasm, it appears that ceftazidime is not adequate single agent therapy for empiric treatment of the neutropenic host with fever.[15]

Third Generation Oral Cephalosporins

There is only one oral third generation cephalosporin available, cefixime, but look for dramatic expansion here over the next five years. Cefixime has *very* poor activity against Gram-positive cocci and activity against Gram-negative bacteria similar to other third generation cephalosporins, but of course, similar blood levels cannot be obtained. I agree with the Medical Letter's opinion that there is little usefulness for this drug.[16] An exception is the recent report that a single oral dose of cefixime 400 mg is as effective as intramuscular ceftriaxone 250 mg for treatment of uncomplicated gonorrhea.[17] If confirmed, this may become a treatment of choice.

The Future

As mentioned above, efforts continue at development of orally active agents with the in vitro antimicrobial spectrum of third generation cephalosporins. The combination of cefoperazone and tazobactam may be marketed soon. Cefpirome and cefepime are parenteral third generation cephalosporins in development; both feature antistaphylococcal and antipseudomonal activity.

Summary

Hopefully this review has brought some cephalosporin contentment to replace cephalosporin confusion. From the classification of these antibiotics in Table 1, we have made some significant reductions. One should know how to use cefazolin for staphylococcal/streptococcal infections and for surgical prophylaxis. One should know that cephalexin is massively overused, and really now not all that useful an agent. Cefuroxime is a useful agent for β-lactamase producing *H. influenzae* infections. Cefotetan has a role in surgical prophylaxis in ob/gyn and represents the best antianaerobic activity of the cephalosporins; although no cephalosporin is a primary drug for anaerobic infections. Cefuroxime axetil or cefprozil can be useful for comparatively minor infections due to β-lactamase producing *H. influenzae*. A third generation cephalosporin represents a reasonable alternative, in certain situations, to aminoglycoside therapy for infections due to multiply drug-resistant Gram-negative bacilli. Ceftazidime is an alternative antipseudomonal β-lactam antibiotic.

Despite the lack of indications for use of cephalosporins as drugs of choice, rational use of these agents can provide safe, effective, and efficient therapy for a variety of infectious diseases. They will likely remain an important part of the physicians' antimicrobial armamentarium for the foreseeable future.

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Occupational Illness in Oklahoma

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This study estimates the extent of work-related chronic disease fatalities in Oklahoma. Occupational cancer, pneumoconiosis, and chronic respiratory, cardiovascular, renal, and neurological diseases are addressed specifically. Also, the costs of chronic occupational illness are estimated.

Because many cases of work-related disease find their way to the primary care physician, an individual who often has little formal training in the recognition and diagnosis of occupational or environmental illness, the education of primary care physicians and medical students in occupational disease recognition and prevention is encouraged.

Anyone working in occupational medicine is aware of the challenge in determining the relationship of occupation to disease. For acute traumatic injuries, cause is relatively easy to determine. However, finding the cause of chronic repetitive injuries or disease is more difficult. The most difficult cases involve illnesses with multiple causes, such as cancer, heart disease, renal disease, neurologic disorders, and chronic respiratory conditions. Occupational medicine specialists are interested in identifying occupation-related illness so that causality can be determined. Only then can those specialists work toward preventing new cases.

Landrigan and Markowitz[1-3] developed a proportionate attributable risk approach to estimate occupational disease mortality in the states of New York and New Jersey. Their study used estimated percentages of disease cases attributable to occupation. These estimated percentages were selected from a range found in the literature.[4-6] The following estimates were used: 10% of all cancer, 100% of all pneumoconiosis, 1% to 3% of all chronic respiratory disease, and 1% to 3% of all cardiovascular, neurologic, and renal conditions. These percentages were applied to disease-specific mortality data from New York and New Jersey to obtain an estimate of the expected numbers of deaths from occupational exposure. The researchers found that, except for pneumoconiosis, the average number of annual occupational disease-related deaths reported by the Workers' Compensation Court in New York and New Jersey was much lower than the estimated number of expected job-related deaths.

There are several possible explanations for the difference between the totals: (1) Only mortality data were used in these studies; therefore, nonfatal cases were excluded. (2) Death certificate data were used by the state to determine cause-specific mortality. The cause of death recorded on death certificates is frequently inaccurate and tends to vary according to the specialty of the physician completing the death certificate, the nature of the illness leading to death, and the length of time the physician had been treating the patient.[7] (3) Workers' Compensation Court data and state vital statistics data are coded prior to statistical analysis; improperly coded data are not uncommon and vary with the experience and indi-

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vidual interpretation of the coder. (4) Finally, the results of these studies are only as valid as the estimated percentages of disease attributable to occupation. The validity of estimates of this type are a subject of debate.[4-6]

In an effort to quantify Oklahoma's success in identifying deaths due to occupational illness while recognizing the above limitations, the Landrigan and Markowitz model was applied to Oklahoma's statistics.

Methods

The State of Oklahoma Workers' Compensation Court Annual Reports of 1988 and 1989 data on disease-specific work-related fatalities were averaged.[8,9] The average annual numbers of work-related fatalities are reported for the following disease categories: cancer, chronic respiratory disease, pneumoconiosis, and a single category containing cardiovascular disease, renal disease, and neurologic disorders (Table).

The numbers of disease-specific deaths for 1988 and 1989 were also averaged and are reported in the Table. These figures are from the Oklahoma State Department of Health.[10,11]

To obtain the estimated number of occupation-related deaths, the number of average annual disease-specific deaths was multiplied by the estimated proportion of disease attributable to occupation (Table).

Results

The estimated average number of annual occupation-related cancer deaths was 648. The average number of annual occupation-related cancer deaths reported by workers' compensation was eight.

The estimated average number of annual deaths from pneumoconiosis was seven, but only five were reported by workers' compensation. The total number of pneumoconiosis deaths for the combined years of 1988 and 1989, reported by the Oklahoma State Department of Health, was 13. Of these cases, four resulted from coal worker's pneumoconiosis, four from asbestosis, one from silicosis, and four from unspecified pneumoconiosis. In comparison, workers' compensation statistics recorded a total of ten pneumoconiosis deaths for the combined years of 1988 and 1989. All ten were listed as asbestosis, and all were reported in 1989. No pneumoconiosis deaths were reported by workers' compensation for 1988.

The estimated average annual mortality from occupation-related chronic respiratory disease ranged from 12 to 37. The average according to workers' compensation records was nine. The annual workers' compensation reports record respiratory deaths as either "upper respiratory" or "influenza, pneumonia, asthma, and bronchitis." These reports do not distinguish between chronic and acute respiratory conditions, except for asphyxiation and pneumoconiosis. Because we were unable to exclude some of these acute conditions, we assumed the nine average annual deaths reported by workers' compensation probably included both acute and chronic respiratory deaths. The estimated average annual number of occupation-related deaths in the combined category of cardiovascular disease, renal disease, and neurologic disorders ranged from 137 to 412. The average

Table 1. Average Annual Estimates of Occupational Disease Mortality 1988 and 1989 in Oklahoma

Cause of Death	Mortality	Estimated Proportions and Number of Deaths Associated With Occupation		Occupational Disease Deaths Reported by Worker Compensation
		%	N	
Cancer	6,484[a]	10	648	8
Pneumoconioses	7[b]	100	7	5
Chronic Respiratory Disease	1,229[c]	1-3	12-37	9
Cardiovascular/Renal/Neurologic	13,725[d]	1-3	137-412	72[e]
Other	8,182	—	—	89
Total	29,627	—	804-1104	183

[a]ICD 140-165, 170-208
[b]ICD 500-505
[c]ICD 490-496
[d]ICD 580-589, 330-337, 430-359, 401-405, 410-414, 420-438
[e]Includes all heart conditions, renal disorders, neurologic disorders and cerebrovascular disorders.
Sources: Oklahoma Health Statistics, 1988-1989
State of Oklahoma Workers' Compensation Court Annual Report, 1988-1989

number of annual deaths actually reported in this category was 72.

Under "cause of death," the category of "other" referred to causes of death not otherwise specified and was not analyzed.

Our findings reflected a total estimated annual average of 804 to 1,104 occupation-related deaths in Oklahoma during 1988 and 1989. During the same time period, workers' compensation records reflected only an annual average of 183 occupation-related deaths.

The Cost of Occupational Illness

The expense of illness can be divided into direct and indirect costs. The costs of diagnosis, treatment, and other goods or services needed to accommodate the illness are referred to as direct costs. Indirect costs are based on lost economic productivity.[20]

The US average annual direct cost per case of cancer in 1975 was $10,595.[20] Based on the estimated number of occupation-related cancer cases per year on average in Oklahoma for 1988–89, and the cost per case adjusted for medical care inflation using the medical care price index, the estimated average annual direct cost of occupation-related cancer in Oklahoma for 1988–89 is approximately $20 million.[21,22] Because direct cost accounts for only40% of total cost, the estimated total cost is about $50 million.[20]

The average annual cost of respiratory disease in the US in 1980 is $33,120 million.[23] If 1% to 3% of respiratory disease is a result of occupation, and Oklahoma represented 1.25% of the US work force on average in 1988 and 1989, then occupation-related respiratory disease in Oklahoma for 1988 and 1989 cost $8 million to $23 million per year on average after adjusting for inflation.[21,24]

Circulatory disease, genitourinary disease, and neurologic disorders cost the US $123,413 million in 1980.[23] After adjusting for the percentage of Oklahomans in the US work force, the percentage of disease resulting from occupation, and medical care inflation, we estimate that, on average, from $30 million to $89 million was spent annually in Oklahoma for these conditions in 1988 and 1989.

The estimated total cost of occupation-related cancer, respiratory disease, circulatory disease, genitourinary disease, and neurologic disorders on average per year in 1988 and 1989 is $88 million to $162 million, based on the US average. We are unable to adjust these values specifically for Oklahoma because Oklahoma medical cost indices are not available for these years.

Conclusions

In all cases, the actual number of deaths reported by workers' compensation was less than the estimated number of occupation-related deaths. This discrepancy was most dramatic for cancer. In the New York study, the average number of annual deaths from cancer reported by the court was three. In the Oklahoma study, we found six deaths. The improvement in reporting seen in the present study compared to the New York study may reflect an increased awareness of occupation-related cancers. In the literature, the estimated proportion of occupational cancers ranges from 1% to 37%.[4-6] To obtain a numerical factor for comparison, the estimated average number of cancer deaths due to occupational exposure was calculated at the conservative end of the range. Using 1%, 65 expected deaths due to cancer was projected. Using the most conservative estimate, the estimated number of deaths due to occupational cancer was still eight times greater than the number of reported deaths.

The estimated proportion of 1% to 3% for chronic respiratory and cardiovascular, renal, and neurologic disease, is also a subject of debate.[12,13] In these categories, the results again reflect some improvement in reporting compared to the New York study. Our findings show a total of 129 deaths due to heart conditions, 13 from cerebrovascular disease and other vascular conditions, and one neurologic death. No renal deaths were reported. This trend may reflect a greater awareness of occupational effects on the cardiovascular system.

There are several agents associated with work-related cardiovascular disease. Well-supported evidence exists for carbon disulfide, carbon monoxide, fluorocarbons, hydrocarbons, methylene chloride, and nitrates.[14] However, many compensation cases do not involve any of the aforementioned agents.

Since work-related pneumoconiosis, unlike the other diseases in this study, is generally an easier diagnosis, we anticipated the expected number of deaths to be very close to those actually reported. In the present study an annual average of seven deaths was expected, but only five were reported. A possible explanation for this difference is that four of the known pneumoconiosis deaths reported by the health department were attributed to coal miners' pneumoconiosis. Since coal mining is not a major industry in Oklahoma, it is possible that those exposures occurred in another state in which mining is a larger industry. If that were the case, those claims would not have been filed in Oklahoma.

The physician should always obtain a thorough history from the patient. Such a history should include medical, family, leisure, and occupational information. Many physicians neglect to take an occupational history and therefore lack a "...logical framework for assessing the significance of reported exposures. Opportunities for the proper diagnosis of occupational disease and for preventive and therapeutic intervention are, therefore, lost."[15] A recent article by Landrigan and Baker outlines one approach to taking an occupational history.[15]

When dealing with an individual patient, physicians must rely on known occupational causes of cancer, heart disease, etc. Being aware of sentinel health events is crucial. A sentinel health event is a preventable illness or death that signals the need to investigate an occupational or environmental exposure as the cause.[7,16] Two of the most widely recognized sentinel events are mesothelioma in asbestos workers and bladder cancer in rubber and dye workers. A less common example is malignant neoplasms of the nasal cavity in wood workers. The importance of recognizing these as sentinel events cannot be overstated. Failure to do so allows the continued exposure of other workers to go unnoticed. Many of these exposures can be easily reduced or eliminated by the use of personal protective equipment such as respirators, or by changes in work practices. It is important that the treating physician bring concerns to the attention of the company physician, or the consulting occupational medicine physician.

When a physician works with several employees in a particular company, rather than an isolated patient, the opportunity to discover unknown health hazards presents itself. It has been estimated that only 10,000 of some 60,000 chemicals used today have been tested for toxicity.[17]

Primary care physicians in rural Oklahoma frequently are in a position to play an important role in early detection and prevention. Rural physicians can best fulfill this role by gaining as much knowledge as possible about the procedures and practices of local industries, and by becoming astute observers of unusual trends or clusters of disease.

Medical surveillance, disease registries within industry, and community-based disease registries offer the opportunity to see trends that may lead to an expanded list of sentinel health events.[18] Surveillance is an ongoing process that involves collection, analysis, and interpretation of data.[19] Primary care physicians are involved in this process as they complete a death certificate. The importance of accurate death certificate data, such as the underlying cause of death and occupation of the deceased, cannot be emphasized enough.

The importance of accurate death certificate data, such as the underlying cause of death and occupation of the deceased, cannot be emphasized enough.

Identifying work-relatedness for diseases with multiple causes and long latencies is difficult. Many of these cases find their way to the primary care physician—an individual who often has little formal training in the recognition and diagnosis of occupational or environmental illness. A study recently prepared for publication by the Occupational and Environmental Medicine Division of the University of Oklahoma Health Sciences Center, entitled "Teaching Occupational and Environmental Medicine (OEM) in United States Medical Schools," polled 100% of the medical and osteopathic schools in the United States and Puerto Rico. Only 52.4% of the schools had class instruction in occupational medicine, and only 32.6% offered rotations in this specialty.

Physicians need to be aware of the resources and consultative services available to them. The American College of Occupational and Environmental Medicine (ACOEM) is one such resource. Several government agencies are also available: (1) the Occupational Safety and Health Administration (OSHA), (2) the National Institute for Occupational Safety and Health (NIOSH), and (3) the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR publishes case studies in environmental medicine. These case studies deal with a variety of toxic substances such as radon, lead, and arsenic. They are designed for the primary care physician; CME credit is available. Resources within the state of Oklahoma include the Oklahoma Occupational Medicine Association and the Division of Occupational and Environmental Medicine within the Department of Family Medicine at the Health Sciences Center.

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SPECIAL

No Joinin' Fees

Richard Green

Retired doctors in Oklahoma City have an opportunity to get together once a month to share war stories, family news, and friendship.

The Retired Doctor's Club was such a good idea that when its founder and guiding light, Dr. Hervey Foerster, died in 1991, the club didn't die with him. Foerster, an Oklahoma City dermatologist, organized the group in 1983, when he was 80, as "the only damn club I know of that doesn't have joinin' fees."

Informal it was and informal it remains under Hervey's successor, Dr. Phil Tullius, an Oklahoma City anesthesiologist. The monthly get-togethers (second Tuesday) are social occasions wrapped around a guest speaker who spends a half hour discoursing on anything except medicine. At least, usually.

But on a bright cool day early last spring, the guest was Dr. Ann Creager, a first-year ob/gyn resident at OU who would present a slide show about her two months' experience working at a medical mission in the central African country of Niger.

The first member to arrive at 11:20 AM was Dr. Willis Lemon, a radiologist formerly with the OU Health Sciences Center. He perused the buffet—sandwiches, salad, soup, and beverages—which had been set up in their regular location, a basement conference room of the Mercy Health Center.

The club used to meet at Baptist Medical Center, where Hervey was on the medical staff, but after his death the club's digs shifted to the north. If the club had a manager, she would be Regina Randall, a Mercy staffer who sends out the monthly meeting notices to the 86 club members on the roster and arranges for the club's room and buffet lunch. Everything is donated by Mercy.

Lemon had looked forward all morning to telling his friends about his recent trip to Alaska. When a visitor arrived and Lemon, who is normally reserved, introduced himself and immediately began talking about his trip. "We visited my daughter who lives in a place called Talkeetna. It's between Anchorage and Mt. McKinley. And speaking of Mt. McKinley, we hired this plane for a looksee and actually landed on one of its glaciers. It was... tremendous... fantastic...."

Words failed. But other members were arriving. Dr. Paul Lingenfelter of Clinton, who again would have received the prize for longest distance traveled—if such a prize existed. (When Hervey ran the club, he wrapped up each meeting by giving away door prizes, usually three cans of Planter's Peanuts.)

Surgeon Frank Gatchell and Edwin Maier, an orthopedic surgeon, talked about Jess Herrmann, the second neurosurgeon to practice in Oklahoma. Sometimes they referred to Dr. Herrmann in the present tense and sometimes in the past, the way people do when discussing a retiree and they aren't sure if some all-encompassing statement is still true. (He was a great man. He is a great man?)

Maier had recently learned that Herrmann had moved from his Mountain Pine, Ark., home to Oklahoma City's Canterbury Retirement Community. "We could swing by there and bring him to the next meeting," Maier said.

"I'll bet he'd get a kick out of that," said Gatchell.

At about 11:30, Tullius said it was time to eat. The group of about twenty lined up for the buffet. Among them was the guest speaker, Ann Creager, who stood out by virtue of her gender (though two women belong to the club, neither attended this meeting) and age (she looked like a visiting granddaughter.)

Quips and wry remarks, mainly associated with the anatomy and physiology of aging, were heard along the line.

Like every good caterer, Regina Randall hovered around the buffet table, being attentive and accepting compliments from the club members about the day's buffet and how well the Retired Doctor's Club is treated generally by her and Mercy.

"That's *tired* doctor's club," someone said.

Tullius greeted Jack Records, an Oklahoma City ob-gyn, who had heard about Creager's African service and thought the club would be interested in her presentation. As club president, Tullius usually has to arrange for the speakers, and coming up with good ones month after month is the most time-consuming part of his role. But the sky's the limit on subjects, which have included politics, gardening, investments, insurance, sports, and travel.

"Actually, I need to get busy coming up with a speaker for next month," he said, looking at the diners, who were a bit inhibited conversationally because they were all seated facing the podium, in a typical classroom configuration. But the seating arrangement didn't stop a fair number of insults and barbs from being hurled across tables; the subjects, in descending order of volume, were attire, physical appearance, and relative prosperity.

After lunch and an introduction by Records, Creager began her slide show. Her experience interested many of these elderly physicians because some of what they saw and heard reminded them of their practices during the Great Depression. They have vivid memories of human deprivation and their own limitations in the pre-antibiotic era.

Creager worked for two months in Galmi, Niger, in a mission that combines the teachings of Christ (in an overwhelmingly Muslim country) with medical ministrations. The Hospital de Galmi, where she worked, is the best in the country. "They call it the hospital where God works because of all the 'miracles' that have occurred there," she said.

Creager showed several slides... mainly of very sick, deformed, or injured people who got better. Most of these patients were first treated by witch doctors, whose therapies generally resulted in their patients' conditions going from bad to worse. One slide pictured a 3- or 4-year-old boy with a great bulging eye tumor. "If his parents had brought him to us before the witch doctor, his eye probably could have been saved," Creager said. "When the parents were told that the eye would have to be removed, the family just took the boy and disappeared."

Other slides depicted common health problems in Niger that haven't shown up much on morbidity and mortality reports in America since the 1930s: malnutrition, severe diarrhea, intestinal parasites, and melon-sized goiters.

The doctors sat attentively during the presentation, and then Ed Munnell, Oklahoma City surgeon, asked, "Why is Niger in such desperate straits?"

Creager said that Niger is supposedly the second poorest country in the world. "The per capita income is about $2 a month. Niger has few natural resources, and no way to tap them. Most people are subsistence farmers, trying to eke out a living in a country in a perpetual drought. Onions are the only cash crop."

Her slides, illustrating most of what she describes, had an emotional impact and stimulated more questions. Everything from diet and wardrobe to politics and economics was asked about. The session ran long. Creager ended with an appeal. "You doctors not only have a great amount of knowledge, you also have great wisdom, and there are lots of places like that hospital in Galmi. I'm asking you to consider donating some of your time and talents to help people whose needs are simultaneously immense and fundamental."

Some of the retired doctors obviously are not physically up to living even a week in a place like Galmi. But others, despite all the jokes about decrepitude, seem strong and robust. And though they are retired, the best qualities that led them into medicine in the first place likely are alive and well and just waiting to be restimulated for some good cause.

Meanwhile, there's next month's meeting to look forward to. And as one of them said in a newspaper article on the club a few years back, "The meetings are one of the only things that keep us going... besides pallbearing and doctors' appointments."

Physicians who are retired or about to be and want more information on the Retired Doctor's Club should contact Dr. Phil Tullius at (405) 843-0639 or Regina Randall at the Mercy Health Center, 755-1515.

The Author

Richard Green is a free-lance writer in Oklahoma City. He is best known to JOURNAL readers as the author of the Leaders in Medicine biographies.



Leaders in Medicine:
Mark R. Johnson, MD

Story by Richard Green
Photographs by Robert H. Taylor

"On the few occasions I've found myself in agreement with the general public, I've had serious pause to reconsider my position."

—Mark Johnson paraphrases Mark Twain

On a September afternoon, Dr. Mark R. Johnson is ensconced in one of his three offices, explaining how he, a man of nearly 70 years, has come to have three different jobs.

At an age when most people have packed it in, he is medical director of Aetna Medicare, medical director of the Board of Medical Licensure and Supervision, and completing his 37th (and final) year in the private practice of internal medicine.

"I'll never forget that day—it was in 1988 sometime—noticing that my car was running on empty and I needed to buy some gas," Johnson continues. "Then I realized that I had a total of seven dollars on me and nothing in my bank account. I thought, *this is getting pretty scary.*"

Johnson speaks slowly and precisely. Not infrequently, gaps of two or three seconds punctuate the clauses of his speech. He chooses words meticulously, just as he did for 20 years as editor-in-chief of this journal.

He wrote more than 200 editorials and often his well-chosen words and opinions stimulated further thought and conversations among colleagues. Less often, his editorials provoked direct responses from readers. At a meeting a few years ago, he gleefully produced a letter he'd just received from an attorney inviting him to relocate to Moscow.

But in recounting that black day in 1988 and how he'd come to such a low point financially and emotionally, he says: "For the first time, I knew what clinical depression felt like."

But he bought four dollars' worth of gasoline and, in due course, found that his own reservoir of strengths wasn't exhausted. As Karl Menninger said, "Unrest of spirit is a mark of life."

* * *

The roof fell in on the Paul Johnson family in 1928. Earlier that year, Paul Johnson had been promoted to a junior executive's position with the Goodyear Tire and Rubber Company. The position, at the headquarters in Akron, Ohio, came with a large well-appointed house tended by a grounds keeper and housekeeper.

For the family of five, which always had lived hand-to-mouth, it was a new experience. And one they were just accommodating to... when Paul Johnson suffered another relapse.

"My first inkling that something was wrong with my father," says Mark, who was then 5, "was when I came down to breakfast and saw some leather manacles on the table. When I asked my mother what they were for, she burst into tears."

He learned later that the restraints had been accidentally left behind by the police who had taken his father to a mental institution. For years, Paul Johnson had suffered from periodic episodes of a manic-depressive syndrome.

Generally, he was hospitalized for a few months until his psychosis passed. His treatment involved a series of hot baths and such, which he recognized were "snake-pit techniques."

When he got out of the hospital in 1930, his job with Goodyear was over and so was the family's chance for financial stability.

But the family had never been close. Though Johnson says his father was intelligent and resourceful, he was also a product of an unhappy and sometimes traumatic childhood and a periodic captive of his mental disorder. "My father never wished me a happy birthday or gave me a birthday or Christmas present," Johnson says. "He congratulated me for accomplishments perhaps two or three times."

Johnson says his mother, Myra, spent most of her time "cultivating the waning relationship with my father. In the process, she managed to attract my sister and alienate my older brother (Paul Jr.). My father defended him against her unfair attacks. Estrangement was palpable all through our family life."

The father's periodic hospitalizations almost always resulted in the family's relocation, occasionally with relatives. By Johnson's high school graduation, he had lived in eight communities in four states, and attended 12 different schools.

Such disruption caused the youngster to be so-

In a class that one OU medical professor said was the best he'd seen in 30 years, Johnson finished in the top five scholastically.

cially withdrawn. "I literally could not understand what close friends were. And when we moved from Akron to Chandler, Okla., I was referred to as the 'sissy Yankee' because my mother dressed me in Little Lord Fauntleroy outfits to go to school with boys who wore bib overalls. Naturally, I was obliged to become somewhat pugilistic to survive.... I remember having fighting appointments."

Though Johnson's family life was unhappy, he was more comfortable in the classroom and by age 10, got his first job selling magazines on a Duncan street corner.

Before he graduated from Chandler high school, he had been a paperboy, janitor, fry cook, soda jerk, yardman, motion picture projectionist, typewriter repairman, and secretary. And he says he enjoyed them all, though a part of his enjoyment probably was derived from simply not being home.

During his senior year, a more gregarious Mark evidently emerged from what had been an asocial adolescent. He was elected president of the senior class and named editor of the student newspaper. In fact, it was named the outstanding student paper in the state, interrupting a victory string, Johnson notes ruefully, that was held by the same Tulsa high school that earlier had rejected his request for a staff position.

That same year his mother died, freeing him, in a sense, from the stifling influence of the unhappy, family. More importantly, the circumstances of her death led him toward a career in medicine. "She died from lobar pneumonia, and I just thought that her medical and nursing care had been totally inadequate," Johnson says.

Years later, he discovered that potentially life-saving sulfa drugs that were generally available at the time had not been administered.

Johnson decided to attend OU in Norman and then the medical school. Some of his friends and family ridiculed his decision. How could he possibly pay for a college education, much less a medical education? A lack of money had forced his brother Paul to quit his chemistry studies at OU when their mother died.

Many of his classmates took relatively high-paying jobs in defense plants following graduation. Mark's maternal grandfather thought that he, too, might be tempted. So, this benevolent gentleman told him: "They are not paying for your skills or talents; they are buying your youth. Spend your most precious possession, your youth, on yourself. Don't let anybody buy it from you. Go into one of the professions."

As far as Johnson was concerned, that settled that. And he set off on foot for Norman in 1940.

* * *

College was a means to an end. Basically, Johnson studied and worked. He lived in a succession of basement rooms and ate most of his meals at fraternity and sorority houses, where he did kitchen chores. This was galling work to one who had tried unsuccessfully to date sorority girls and pledge a fraternity. He was refused admission because he had a job with the National Youth Administration, a federal jobs program. He bitterly resented this exclusion and other humiliations suffered because of his disenfranchisement from the privileged class. Fortunately, he had little time for emotional smoldering.



In 1946, Mark Johnson had just earned his medical degree from the University of Oklahoma School of Medicine.

He took 17 to 22 hours a semester and, unfettered by a social life or other extracurricular activities, did well scholastically. He was one of nine juniors named to the President's Honor Class.

It was the custom to honor these young scholars at dinners held

periodically at fraternity houses. When Johnson showed up for the festivities, he relished seeing the surprise of the members and housemothers, who had known him only as kitchen help.

After entering OU's medical school in the spring of 1943, Johnson's class was immediately mobilized and shipped to Ft. Sill for induction training. Thus, the immense problem of financing a medical education was erased; as private first class, he received a housing allowance, was paid $58 a month, and his books and fees were paid.

Medical school suited Johnson's needs to a T. He was intellectually motivated and emotionally satisfied. "For the first time, I had close friends."



When Mark Johnson was sworn in as a member of the University of Oklahoma Board of Regents in 1960, he was the youngest person ever to have held that post.

And having become a bona fide member of what he thought of as sort of a family, he was anxious to demonstrate that he belonged. His grades and aptitude were excellent. In a class (1946) that one OU medical professor said was the best he'd seen in 30 years, Johnson finished in the top five scholastically.

Moreover, he started and was the first editor of a medical student newspaper, the *Apex Beat,* which served as another outlet for his creativity and opinionated nature. He also helped develop a student council, a more formal pipeline to the school's administration and the university.

Johnson and classmate Raymond Hinshaw used both forums to propose that black people be admitted to the medical school. While the OU Board of Regents sympathized unofficially, its hands were tied, as integrating the medical school was against state law.

Though the proposal was sincerely made, it was evidence of what Johnson called his "iconoclasm." He was becoming fond of paraphrasing Mark Twain's aphorism: "On the few occasions I've found myself in agreement with the general public, I've had serious pause to reconsider my position."

One of his classmates, the late Dr. Edgar Young, called Johnson "an angry young man. If there wasn't a windmill to tilt, he'd look for one."

Johnson was attracted to a professor who not only taught him anatomy but also served as his role model. Ernest Lachman was a radiologist and Jewish intellectual who fled Hitler's Reich in 1936 and wound up in Oklahoma. Part of Johnson's initial attraction was his temerity (briefly) to identify the alienation he felt in college with the social ostracism suffered by Lachman under the Third Reich.

When Lachman showed interest in Johnson, he responded by expanding his professor's status to include father figure and medical mentor. "Dr. Lachman was one of the few true classical scholars on the faculty," says Johnson. "Yet, he was a humble and warm person. He was a great inspirator; he taught us the importance of compassion and honesty in maintaining scholarly pursuits and eschewing mercenary considerations. He stood for everything I've tried to accomplish in my career."

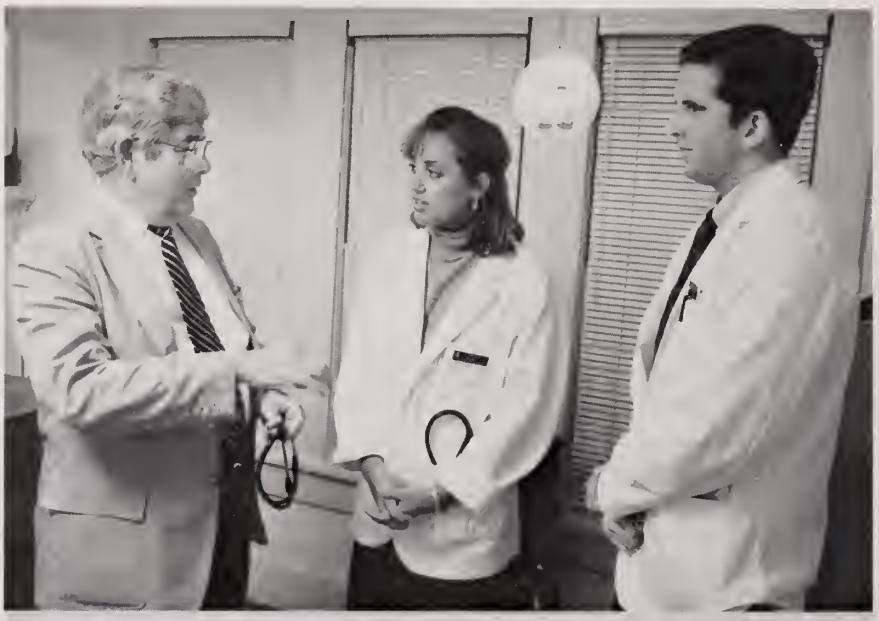
* * *

Johnson was introduced to Ruth Tarpley at a college party in 1942. They exchanged pleasantries and parted company. Three years later, they met again in Tulsa, where Ruth and her mother were renting an apartment from Johnson's father. (Evidently, some things are just meant to be.) Johnson asked Ruth to dinner.

They were married the next year, six weeks into Johnson's internship at the University of Wisconsin in Madison. He had warned Ruth that she would be marrying "a bigamist," medicine being his "first wife."

The internship was pivotal to his career because he was exposed to world-renowned internist Dr. William S. Middleton. After leaving Middleton's service, Johnson knew he couldn't be happy unless he went into internal medicine. He planned to return to OU for his residency in 1947, but events, not his predilections, were in the driver's seat.

Six years would pass before Johnson would begin his residency training in earnest. The medical school's new dean declared that only combat veterans would be given residency positions. Since it was too late to apply elsewhere, Johnson notified the War Department that he was available for active duty.



Johnson works evenings at the Little Flower clinic in Oklahoma City. Here he chats with Stacy Corlett (c) and Brad Carter (r), both 2nd year students at the OU College of Medicine.

Meanwhile, he became director of the Cleveland County Health Department. Though he knew next to nothing about epidemiology, he began the job with customary bravado. As an example, he angered some of the county milk producers when he ordered the strict enforcement of grade A milk standards. The action was taken after his staff had shown that some contaminated milk was causing cases of strep throat.

Johnson decided to invite them to a Saturday morning meeting to explain the problem and answer questions. The auditorium was packed and the audience was "decidedly unfriendly." Since Johnson was only 24, he apparently decided to add a bit of theater to his presentation. "I walked in unshaven wearing a filthy white coat, soiled trousers, and a stethoscope around my neck and asked the audience if they'd like me to take care of their wives and children.

"Well, they all laughed and the ice was broken. Then, I explained that we were allowing unclean milk into the marketplace and that the strep throat cases could lead to much more serious illnesses such as scarlet fever and rheumatic fever."

The meeting ended amicably and the strep throat epidemic passed. But a typhoid epidemic in nearby Purcell led to Johnson's next job. Dr. Bill McCurdy called Johnson to say he was inundated with patients and desperate for help. Because Johnson was anxious to get back to clinical medicine, he volunteered to help.

Then both physicians were inundated with patients. Six days a week, they saw clinic patients, made house calls, delivered babies, did surgeries, and attended to trauma cases. They also worked some on Sundays to accommodate those who only came to town for church.

After a few weeks, Johnson recalls, "I was running out of energy and enthusiasm. In most cases, it seemed like all we were doing was *seeing* patients. I thought most of them could have been treated symptomatically just as well by a good pharmacist."

So, Johnson came to appreciate the difference between an internist and a GP. "A GP commits to a community; he is limited by time, not skill or sincerity. An internist makes a commitment only to the patient."

In January 1948, after six months of this breakneck medicine, Johnson was called to active duty. "I was absolutely exhausted," he says.

* * *

The most noteworthy event of Captain Johnson's 20-month tour in the Azores Islands was the birth of Mark C. Johnson in Oklahoma City, the first of the Johnsons' four children. In March 1950, Johnson left active duty and accepted an appointment to direct the student health service on the OU medical center campus until July, when his long-

delayed internal medicine residency would begin. The Johnsons' second child, Joy, was born in May.

Since his residency wouldn't pay much, Johnson decided to supplement his income by joining the national guard, the famed Thunderbirds of the 45th Division. But in late June, the North Koreans invaded South Korea, and three months later, the Thunderbirds were activated.

"I was chagrined, yes, but not angry," says Johnson, who figured his infantry division would get right in the middle of the war.

Correct again.

The experience began ominously. Johnson's outfit landed in Korea on Thanksgiving night in a sleet storm. An epidemic of hemorrhagic fever, a disease with a mortality rate of 80 percent, was raging in that area. "Initially, it was more frightening to us than the prospect of combat."

Major Johnson was in charge of a 500-person medical battalion responsible for treating and evacuating casualties and for preventing and controlling infectious diseases. Of the five divisions operating around the front lines, Johnson's was graded number one in terms of medical service. He was awarded a Bronze Star and a Meritorious Service Medal from the 45th Division.

He says part of his success was due to advice from a retired master sergeant in San Antonio. "He told me if I'd learn the army regulations pertaining to medical issues, nobody would ever abuse me, and I'd get promoted up the administrative chain. Made sense, so I memorized the entire manual."

* * *

When Mark Johnson finally got to his residency, he found it somewhat frustrating. When he compared his clinical abilities to those of his superiors, Drs. Robert Bayley, Stewart Wolf, and Robert Bird, he came up decidedly short. A resident comparing himself to that august group may seem arrogant. But he wasn't exactly a callow youth.

A second daughter, Janice, was born during the residency, and then two years later the family was complete with the birth of Stephen.

In 1955, Johnson established a private practice and joined OU's volunteer faculty. He became involved with organized medicine because he thought the public image of physicians needed changing. He volunteered to be the Oklahoma State Medical Association's liaison to the state Welfare Department during the late 1950s when its director, Lloyd Rader, was developing an assistance program for the medically indigent.

In 1958 he became secretary-treasurer of OSMA. He began a second term in 1960, but his participation in the socioeconomic and political aspects of medicine went on a virtual seven-year hiatus when, to his astonishment, he was appointed later that year to the OU Board of Regents. When the Johnsons lived in Norman years before, they had socialized with another young couple named J. Howard and Jeanette Edmondson. And now, Governor J. Howard Edmondson proposed to appoint Johnson to the OU board. Johnson recalls, "I said I would be pleased to accept, but I reminded the governor that by appointing someone else, he could pay off a political debt. He said his mind was made up."

Later, Johnson heard that the governor had refused a substantial amount of money to appoint someone else.

* * *

Mark Johnson always had though of the medical center campus as the university's stepchild. So, he immediately proposed the creation of a regents' subcommittee, which he was named to chair, on the Oklahoma City campus. Ideas percolated out of the subcommittee: Move the college of pharmacy from Norman to Oklahoma City. Organize a college of allied health professions. Build student dorms and a student union at the medical center.

Johnson was especially pleased with the establishment of the Regents Award for Excellence in Teaching, which he suggested. The award provided a substantial monetary recognition of excellence in classroom teaching and would complement similar



One of Johnson's duties as medical director at Aetna Medicare is going over claims with Nurse Reviewer Martha Krivanek.

awards already in place for medical research. Johnson also proposed modifying the medical school's curriculum and admissions criteria. "The practice of medicine isn't a science, and practitioners of medicine aren't scientists," he said. "They should be humanitarians, act ethically, and understand honesty."

Accordingly, Johnson thought that the admission policies should minimize science requirements and broaden those in humanities. "Every study I've examined has concluded that the entire meticulous admissions process is no more effective than a lottery," he says.

Whatever changes might be made, it was clear by the early sixties that the medical center's campus was on the verge of tremendous expansion. That is why the selection of the medical school's new dean in 1964 was so important. A leading candidate was Dr. James L. Dennis, a 1940 graduate of OU's medical school. Before supporting Dennis, Johnson shared his plan for instituting a formal linkage between College of Medicine faculty and practicing doctors in the state. He called it the "Visiting Professor Program," and Dennis "certainly seemed enthusiastic about it," Johnson says. That perceived support was an important reason why the regent decided that Jim Dennis was the right man at the right time. Following a vote, Dennis was appointed in September.

According to Johnson's plan, each clinical faculty member would spend at least one weekend per year visiting a practicing physician. "As authorities in their fields, our faculty visitors could make a local presentation or two, and by staying with a physician for a weekend, they could develop an appreciation of what the practitioner's life is like and what his practice needs are."

After the program had been well established, Johnson was sure it would pay permanent dividends to the medical center: "When we needed increased financial support, we could count on these physicians and constituents to go to their legislators endorsing our requests. We wouldn't have to tote the empty brown bag out to the capitol anymore."

A year later, Johnson asked Dennis how he was coming with the program. "He told me, 'Mark, we just can't do it. If I try to make the faculty participate, they'll quit.' I told him if they didn't have that much interest in supporting physicians who are trying to give good medical care in the communities, then we don't need 'em.

"I said, 'Jim, if we get this going, we can forget about being the straw man for every opportunistic politician in the state; we'd have grass roots support.' But he said it couldn't be done."

Later, Johnson realized that Dean Dennis had his own plan, cultivating civic leaders to serve as unofficial patrons of the Oklahoma Health Center, with the College of Medicine serving as its hub. Johnson thought this was the wrong way to garner public support for the institution. But the amazing transformation from small medical center to huge health complex that Dennis promoted and nurtured through the rest of the sixties is evidence of his effectiveness.

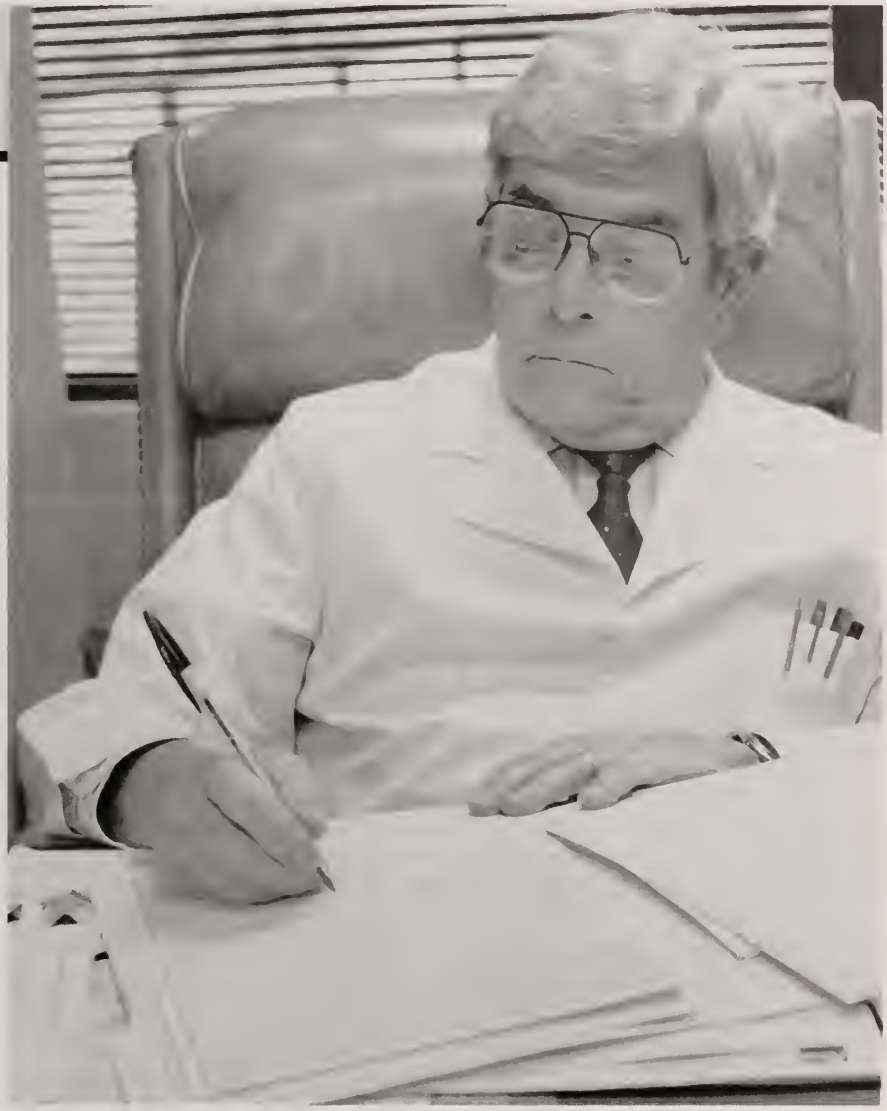
* * *

Less than a year after Johnson's term on the OU Board of Regents ended in 1967, he accepted an "interim appointment" as editor of the OSMA JOURNAL. That was the way it was put by his friend, Dr. Marvin Margo, then OSMA president. Johnson didn't have to be inveigled into taking or keeping the position. It was an ideal vehicle for meeting many of his needs. He was free to express himself about the subjects and issues that mattered most to him.

From the beginning, he wrote provocatively, using crisp clear prose and sarcasm in a "head-on" style of editorializing. A good example is one of his early editorials in which he wrote that all the emphasis being put on the government's anti-cigarette smoking campaign tended "to deprecate by



Johnson visits with his son, internist Mark C. Johnson, MD, in his son's Oklahoma City office.



It's Johnson's last day in private practice, but the paperwork keeps coming.

burial the much greater threat to society of alcohol and drug abuse."

While he wrote that he wasn't endorsing tobacco, "it hurts only the user. Alcohol is associated in four of five hospital admissions, nine of 10 mental hospital admissions, and in 60 to 70 percent of auto accidents." He concluded, "We are firing cannons at gnats and pea shooters at tigers."

The editorial provoked many responses, most negative. He was called an embarrassment to OSMA and the profession. But stimulating some heat along with the light was simply an occupational hazard to Johnson. Sometimes, he even enjoyed it.

In his second decade as editor, some readers noticed an increased hyperbolic tone to his writing. It may have evolved over the years of cranking out ideas and passions into what at times seemed like a void. According to Managing Editor Susan Records, the average editorial provoked only a letter or two.

One of his biggest disappointments was the relative lack of response to a November 1984 editorial titled "Sad Consensus." He wrote it deliberately to fire up his readers. The "consensus" referred to longtime physicians who feel fortunate to be near the end, and not the beginning, of their careers. After all the sacrifices to practice medicine, "we know that today we are being told how, when, where, and with what we can treat patients. We know that lay bureaucrats rule us while only we are liable for the consequences of their rule... we are being enslaved; we are suffering through the humiliating denigration of a profession."

Johnson says he hoped to see how wrong he was, to hear from many physicians saying, "Johnson, you're crazy. The rewards of practicing medicine today are just as great as they've ever been."

Only seven letters were received, and of those who took issue with editor Johnson, none were from physicians still participating broadly in the Medicare or Medicaid programs.

But letters don't necessarily reflect impact accurately. And Records says readership surveys indicated that Dr. Johnson's editorials were easily the most popular feature in the JOURNAL.

* * *

During the decade 1979-88, Johnson was involved in developing comprehensive programs on chronic diseases and rehabilitation, first at OU and later for a private facility.

Though he was at OU for three years, he knew after two that the institution had changed priorities. It happened all the time, for as his experience as an

OU regent had taught him, a university is as political as any bunch of Chicago ward heelers. By his third year, this tenured professor knew he had been frozen out by the leadership. If he was partially or mostly at fault—for wanting to go too fast, for example—he says he never heard.

As his misery deepened in January 1982, Dr. James Pitts called to ask if OSMA could nominate him for a term on what was then called the State Board of Medical Examiners. This prestigious and important appointment was a tonic to one who was temporarily down on himself. He accepted and was soon elected secretary.

A month later he was asked by the Rehabilitation Institute of Oklahoma to design and implement a program that was similar in scope to the one that never materialized at OU. He was getting a second chance to realize his long-held ambition.

He expanded his knowledge by studying the structure and protocol of other rehabilitation hospitals. By 1984 staffing was adequate, the census was high, and referrals were plentiful. Some days there were waiting lists.

The institute had about 40 rehabilitation beds and a 32-bed skilled nursing division. Also, a chemical dependency treatment program was housed in the building. Because demand usually exceeded availability, Johnson said in 1985, "I hope to persuade the owners to develop a rehabilitation park in the metro area. We'd have one building for physical rehab and one for behavioral rehab, and they would share common administration and support facilities. An associated hotel would accommodate patients' families from out of town."

Any hope of implementing his plans disappeared, however, when the owners decided to sell the institute in 1988. And though the new owners wanted Johnson to stay on as medical director, he knew the corporation had its own man to run its kind of program. He had no stomach for staying around as window dressing. So, he resigned and found himself adrift for the first time in his professional life.

He had scaled back his private practice, and there was little left of it. His appointment to the state licensure board ended in 1988, and despite his success updating and modernizing the state's medical practice law, the reform angered a number of physicians, particularly some at OU who personalized their attacks. They said or insinuated that Johnson's motive was revenge against OU.

The issue involved Johnson's belief that persons unlicensed to practice medicine in Oklahoma should clearly be identified as such to the public. According to state law only licensed physicians could use the abbreviation MD after their names. So Johnson devised a new designation, SMD, meaning supervised medical doctor, that would henceforth be used and displayed publicly by all interns and others who, for whatever reason, didn't have a state license.



Mark Johnson and his wife, Ruth, plan another road trip.

This was the major reform in the new medical practice law that Johnson designed and the legislature enacted in 1987. He said the new designation would protect the public and the university's clinical faculty and enable third-party payers (especially the government) to know that claims from Oklahoma have been signed only by licensed physicians.

Despite the applause of other members of the state board and especially the national Federation of State Medical Boards, the personal attacks on Johnson's character cut deep, and the hurt he felt lingered into 1988... to that day when he discovered that he was running on empty.

"Being dogmatic is gainful of nothing. If you are right, everyone will hate you, and if you are wrong, you are a fool."

—Mark R. Johnson, MD

What he needed was an attitude adjustment. Instead of dwelling on recent disappointments, why not ring down the curtain on a long, distinguished, productive career and take Ruth on a long cruise around the world? Because he was not exaggerating when he said he was broke. He had never made profitable business decisions and had no retirement plan.

Johnson's redemption came from a most unlikely source, one of his primary editorial targets for twenty years, the Medicare program. In one of his most scathing pieces from the 1970s, he wrote that "...Medicare beneficiaries are victims of this politically motivated fraud." Medicare "is a parasite masquerading as a host." And so on, in a litany of damning editorials that was almost like a monthly mantra.

And suddenly, so it seemed, here is Aetna Medicare's Fred Bush on the phone asking Johnson to lunch to discuss the medical director's job. Johnson says he was "very impressed by Bush's affability and intelligence." But why would Medicare want to hire such a caustic and chronic critic?

So that physicians would know that the medical director was a colleague, not an adversary. After he accepted, Johnson got a few calls and letters from physicians expressing dismay over his decision to join "them."

"I told 'em I am, in effect, an ombudsman for the medical community."

Much of his work involves reviewing Part B claims that initially seem to conflict with HCFA regulations as they apply to the disbursement of funds by Aetna. Johnson performs his job conscientiously, skillfully, and with aplomb, refusing to trade barbs or insults with physicians whose egos are on the line. "I don't blame them for their hostility," he says.

Many of them don't realize that they don't admit patients to the hospital anymore, he says. "The misconception that they admit patients is a source of much of medicine's greatest agony. The reality today is that a physician's responsibility for his patient has been revoked by some remote third-party payer. The only way a physician can protect himself or herself is to tell the patient, 'Look, your agreement is with your insurance company. If they disagree with me, then I'm gonna have to ask you to find another doctor.'"

Pretty gloomy. He says most of his longtime colleagues are likewise dispirited because they have witnessed the traditional characteristics of the profession disappear. "They no longer determine the value of their services, and when you deprive craftsmen of that ability, you take away their sense of rewards for their accomplishments."

Despite his melancholic attitude toward the practice of medicine, Johnson is not only happy, he appreciates every single new day in a way unique to people who have been brushed by death and come to terms with their own mortality.

In the summer of 1991, Johnson was diagnosed with prostate cancer. Following 18 radiation treatments and surgery, his cancer in September 1992 seemed to be in remission. The bad news is that the cancer eventually will do him in "if something else doesn't first." But the good news is that he lives normally with virtually no pain, and his life expectancy is unknown.

He closed down the last vestiges of his private practice on September 25th, but continues with Medicare and as medical director with the state licensing board. He and Ruth enjoy life perhaps as never before and take long car trips together to medical meetings and to visit their children and grandchildren.

Johnson delights in noting how "successful" he was in preventing his children from acquiring the two worst features of his personality: being dogmatic and not smiling enough. "I told them that being dogmatic was gainful of nothing. If you are right, everyone will hate you, and if you are wrong, you are a fool. They learned this pretty well. I just wish someone had given me such sage advice at an earlier age. But as I wrote one time, 'Wisdom is the result of the exercise of our poorest judgment.'" ℐ

Begun in 1981, the Leaders in Medicine series recognizes some of Oklahoma's most outstanding physicians and the contributions they have made to their communities and profession. This is the twenty-third article in the series.

Richard Green is a freelance writer. Robert Taylor is a freelance photographer. Both are based in Oklahoma City.

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News

OSMA delegates approve 10% assessment on PLICO premiums

Despite wintery conditions and hazardous roads in some parts of the state, members of the OSMA House of Delegates journeyed to Oklahoma City in November for a special session.

The November 22 meeting was called for the express purpose of considering the imposition of an assessment on the premiums paid by state physicians to their professional liability insurance company, PLICO. Under the bylaws of the association, no other business could be discussed at the meeting.

The assessment, necessary to increase PLICO's capital surplus in accordance with pending new federal regulations, was explained in detail and ultimately approved by the delegates.

The assessment will amount to 10% of each insured physician's malpractice premium rates and will be charged each year for the next three years. It will be accompanied by a 5% rate increase for 1993.

Insured physicians who are not members of the OSMA will be billed a policy fee equal to the assessment, plus a non-member fee of $250.

Dr. John A. McIntyre, president of PLICO, explained that capital requirements for the company will increase from $4 million to $14 million in the next three years, and that the 10% assessment would cover the increase. He added that an OSMA assessment was being employed, rather than a PLICO policy fee, because it would not be subject to the $2.5 million in state and federal taxes that would be levied on a fee.

Rod Frates, president of C.L. Frates and Company, which handles PLICO, explained in detail that in recent years the government has changed the capital requirements for banks and savings and loan companies, and is now changing requirements for casualty insurance companies. Actuaries have determined that the 10% assessment will meet these new requirements. Frates also noted that the assessment is independent of any rate changes.

The 10% assessment approved by the delegates, plus the 5% premium rate hike, will raise $3 million per year, or a total of $9 million over the three-year period.

Delegates pointed out that the assessment might end up being unnecessary after the details of the new regulations are released. However, an amendment to return the funds to physicians in that event was defeated.

Delegates also questioned why non-members have to pay only a $250 surcharge. Frates explained that this is the highest amount the state insurance commissioner currently will allow. However, he said, both PLICO and OSMA are continuing their ongoing efforts to persuade the commissioner that non-membership should result in the collection of additional monies.



OSMA delegates contemplate the assessment as...





Rod Frates and Dr. John McIntyre explain why it is necessary.

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Physician Staffing Resources

OSMA trustees hold their November meeting in Oklahoma City

A special award to Dr. George H. Kamp, Tulsa, was at the top of the agenda when the OSMA Board of Trustees convened its November 22 meeting in Oklahoma City.OSMA President James D. Funnell, MD, Oklahoma City, presented a plaque to Dr. Kamp in appreciation for his years of service to the OSMA as a delegate to the American Medical Association. Dr. Kamp was a delegate from 1984 to 1991.

In other business, Dr. Funnell reported that the OSMA Commission on International Medical Graduates has had its organizational meeting. One item under consideration by the commission is bringing foreign medical exchange students to Oklahoma.

Dr. Funnell also reported that the OSMA committee on the Medical Practice Act has met under the leadership of Drs. Richard J. Boatsman, Lawton, and Harry B. Tate, Oklahoma City. The committee, in partnership with similar committees from the University of Oklahoma Health Sciences Center and the Oklahoma State Board of Medical Licensure and Supervision, will make recommendations to the state on how to rewrite the act.

In other actions:

✓ The Executive Committee submitted its recommendations for the OSMA employees' pension plan, and a motion to accept them was approved by the board.

✓ Dr. Garth L. Splinter, from Governor David Walters' office, presented the report of the Governor's Health Care Commission. OSMA board members suggested language to make it clear physicians feel all Oklahomans have a right to access to health services, as opposed to a right to care. Dr. Splinter said the commission's report will have to be studied, made more specific, and go to a vote of the people before it becomes law.

✓ Dr. C.S. Lewis, Jr., Tulsa, who sits on the Governor's Interim Task Force on State Welfare and Medicaid Reform, encouraged the OSMA and PLICO to seriously consider being the company to get a managed care program started in Oklahoma. Mr. Rod Frates, president of C.L. Frates & Company, said it would be better for the OSMA to be the plan administrator and "farm out" the business to a commercial insurance company.

✓ OSMA Secretary-Treasurer Elaine N. Davis, MD, Enid, submitted the budget proposal for 1993. A "budget neutral" plan still subject to approval by the OSMA House of Delegates in April, the proposal was accepted by the board.



OSMA President Jim Funnell (l) presents an award of appreciation to Dr. George Kamp of Tulsa, thanking him for his many years of service as a delegate to the AMA.

✓ The board approved a motion to increase the compensation rate of the PLICO Board of Directors from $50 to $75 an hour.

✓ Mr. Jim Williams, executive director of the Oklahoma Foundation for Peer Review, announced the resignation of Medical Director Michael W. Strange, MD, Stillwater. Dr. Thomas H. Henley, Oklahoma City, will serve as interim medical director while a search is underway for a physician to fill the part-time position. Mr. Williams also reported that the contested positions for the OFPR Board were won by Dr. Guy W. Fuller, Sr., Oklahoma City, and Dr. Michael Kemp, Poteau.

✓ OSMA Hospital Medical Staff Section Chairman William O. Coleman, MD, announced the HMSS will be conducting a conference at the Oklahoma City Marriott on January 30, 1993.

✓ William G. Bernhardt, MD, Midwest City, chairman of the the Council on Member Services, reported that his council had approved an OSMA pension plan incorporating the program developed by the Utica Physicians Association, Ltd. (UPAL) in Tulsa. He also said that the council had approved Mr. Lyle R. Kelsey, OSMA associate director, as a licensed insurance agent to represent the OSMA insurance programs to members.

✓ The board voted that the OSMA not be listed as a sponsor for an upcoming Danube River trip which will include a visit to Serbia.

✓ The board approved Life Memberships for the

(continued on next page)

Health Department

Childhood burn injuries: Butter, ointment, and toothpaste are not the remedy

Each year more than 200 Oklahoma children under 15 years of age are admitted to a burn center or die as a result of burn injuries, accounting for 842 burn injuries from 1988 to 1991. Although comprising only 22 percent of Oklahoma's population, these children accounted for 35 percent of the severe burn injuries. Scalds (tap/heated water, grease, or coffee/tea) accounted for 40 percent of childhood burns, followed by flame/fire (children playing with matches or lighters [fireplay], improper use of gasoline [flammable liquids], or residential fires) at 33 percent, contact with hot solids (irons, heating devices, or coals/ashes) at 22 percent, and chemical/electricity/other at 5 percent.

Children under 5 years of age were most affected, suffering 72 percent of the severe childhood burn injuries; nearly half were caused by scalds. Physicians can advise parents to lower the water heater thermostat to 125°F-130°F and to not let children play in the kitchen while food is being prepared to prevent many of the scald burns. For black children under 5 years of age, the rate of burn injuries is nearly five times that of other children; clothes and curling irons accounted for nearly two-thirds of these burns. Advising parents to iron clothes on countertops instead of the floor (if an ironing board is not available) and preventing electrical cords from hanging within the reach of young children can aid in the prevention of iron burns.

For children ages 5 through 14, half of the severe burns were caused by fireplay and flammable liquids. Teaching children that matches and lighters are tools and not toys, and that gasoline is a highly flammable fuel to be used under the supervision of adults, are prevention strategies that can be conveyed to parents as well as children.

Of the 842 severe childhood burn injuries, 96 were fatal; 84 occurred in residential fires. Functional smoke detectors are a very inexpensive and effective way to prevent residential fire-related injuries. In addition, supervision by a responsible adult, parental awareness of the causes of burns, and the practice of safe habits are essential to the prevention of childhood burns. For more information, call the Oklahoma State Department of Health Injury Division at 405/271-3430.

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Board of Trustees *(continued)*

following OSMA member-applicants: William S. Harrison, MD, Chickasha; William A. Heflin, MD, Ryan; Byron F. Smith, MD, and George L. Winn, MD, Oklahoma City; and Joseph M. St. Ville, MD, Sapulpa. Partial dues exemptions were approved for Charles Bodine, MD, and Melissa K. Clements, MD, Oklahoma City. Affiliate membership was approved for Dr. Richard Carver.

✓ After considerable discussion, the board reaffirmed its position to support the efforts of the American Academy of Ophthalmology, which plans to target Oklahoma for legislation addressing the issue of optometrists performing laser surgery.

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WORTH REPEATING

AMA releases document on economic credentialing

[Editor's Note: The following document presents a concise current summation of where the issue of economic credentialing stands at the moment. Prepared by Denise Andresen, JD, of the AMA Office of the General Counsel, the piece has been printed in the Sept./Oct. issue of the Florida Medical Association Journal, FMA Today, *and is herewith shared with the rest of the Federation.]*

■ **Economic Credentialing: Profitability Versus Quality—** Economic credentialing has rapidly become one of the most controversial practices in hospital privileging. Two years ago, economic credentialing was rarely discussed in health trade journals or medical staff forums. Today, driven by an intensified pursuit of "efficiency," economic credentialing has gained notoriety in concept, if not practice.

The American Medical Association (AMA) defines economic credentialing as "the use of economic criteria unrelated to quality of care or professional competency in determining an individual's qualifications for initial or continuing hospital medical staff membership or privileges."[1] Historically, credentialing has been performed to ensure that applicants for medical staff membership and privileges are professionally and ethically qualified to care for patients in a hospital. Economic credentialing turns the focus from professional qualifications to financial worth; the inquiry is no longer whether the physician is qualified, but whether the physician is profitable.

Documented instances of economic credentialing are few, but rapidly increasing. All indications are that institutions will continue to increase their efforts to implement economic credentialing. A 1989 survey by the American Hospital Association (AHA) showed that only 4.7% of 3400 hospital chief executives had programs linking credentialing with Medicare's prospective payment cost revenue profiles. Two years later, another AHA survey of 500 hospital chief executives showed startling results; 71.4% prepared economic profiles of their physicians and used them for educational purposes, and 41.7% believed that hospitals in the following five years would begin to tie privileging with physicians' economic contributions.[2]

■ **Economic Credentialing and Medical Staff Bylaws—** Economic credentialing is insidious. It is appearing in proposed amendments to medical staff bylaws across the country. Unfortunately, many physicians do not recognize economic credentialing and do not, therefore, resist such amendments. The following case study should alert physicians to the types of amendments that could authorize economic credentialing.

An AMA member requested assistance in responding to proposed bylaws amendments. Although none of the amendments was captioned "economic credentialing," several of the provisions would have authorized the practice. One amendment defined "clinical performance" as appropriate training, current experience, clinical results and utilization practice patterns, documenting a continuing ability to provide patient care services at an acceptable level of quality and efficiency given the current state of the healing arts and consistent with available

Also, "cooperativeness" was defined to include

(continued)

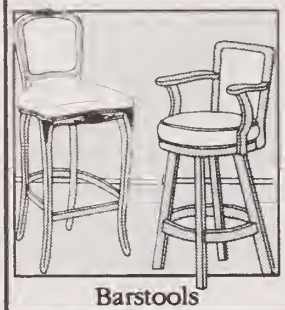
CALL FOR RESOLUTIONS

All resolutions to be presented to the Oklahoma State Medical Association House of Delegates Annual Meeting must be received in the OSMA executive offices no later than thirty (30) days prior to the meeting. This year's meeting will be April 23-25, 1993, at the Tulsa Westin Hotel.

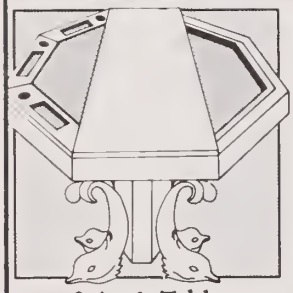
County medical societies or individuals wishing to submit resolutions should mail them to: OSMA, 601 Northwest Expressway, Oklahoma City, OK 73118. Should you need assistance in drafting such resolutions, please contact the executive offices.

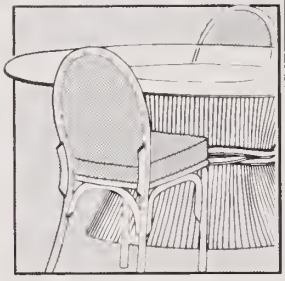
Resolutions must be submitted on or before March 23, 1993

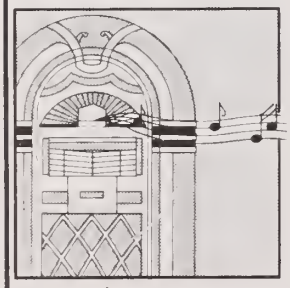
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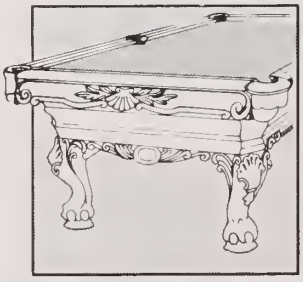

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Economic credentialing *(continued)*

behavior that does not adversely affect efficiency. Finally, the board was authorized, in credentialing matters, to consider the board's policies concerning the Medical Center's current and projected patient care, teaching and research needs and the availability of required physical, personnel and financial resources.

These provisions would have authorized the hospital to apply economic credentialing to physicians who applied for medical staff membership or privileges. Similar provisions could appear in virtually any section of the bylaws, but most frequently are found in the definitions section, membership section, appointment section, privileges section and the "catch all" general provisions section of the bylaws. Authorization to perform economic credentialing typically is not obvious; it could be as general as a provision requiring the staff to "comply with all hospital policies."[3]

■ **Economic Credentialing Is Challenged in Florida Court—** At least one hospital has applied economic credentialing despite the fact that nothing in the medical staff bylaws authorized the practice. On June 16, 1992, the trial court in *Rosenblum v. Tallahassee Memorial Regional Medical Center* concluded that a Florida statute authorized Tallahassee Memorial Regional Medical Center (TMRMC) to deny privileges solely on the basis of economic criteria.

Rosenblum, considered by many to be the "test case" for pure economic credentialing, involved an eminently qualified surgeon who applied for cardiac and thoracic surgery privileges at TMRMC. TMRMC granted the thoracic privileges but denied the cardiac privileges because Dr. Rosenblum had a contract with TMRMC's competitor—and the only other hospital in town—to develop its cardiac surgery program. Dr. Rosenblum filed suit, challenging the hospital's authority to deny his privileges on the basis of economic criteria.

The trial court determined that the medical staff bylaws, which stated that privileges should be granted on the basis of professional criteria, were not applicable because Dr. Rosenblum was an applicant for privileges, not a staff member with vested rights. Turning to state law, the court concluded that a general provision in the Florida Hospital Licensing Act authorized the board to consider economic factors in credentialing matters. The statute allowed the board to consider the qualifications, training and

health status of the applicant, and "such other elements as may be determined by the governing board." "Such other elements," the court concluded, "validly embraces the concept of what is called economic credentialing."

Although the statute authorizes economic credentialing, the court stated, there must be valid economic considerations and they must not be imposed arbitrarily. Because Dr. Rosenblum had a contract with TMRMC's competitor, the court concluded that both tests were met; the contract was a valid economic consideration, and the "intense" competition between the hospitals showed that TMRMC's decision was not arbitrary.

Rosenblum is significant because it is the first court decision upholding pure economic credentialing. Although proponents will argue for a broad interpretation, the decision is narrowly limited by the facts of the case to situations where a physician has a written contract to develop a surgery program for the hospital's competitor. Dr. Rosenblum's attorney has filed a notice of appeal.

■ **Implications of Economic Credentialing—** Economic credentialing has obvious negative ramifications for physicians and patients. Physicians who do not have profitable practices or who compete with their hospitals may lose their privileges. Patients who come to a hospital may receive care by physicians who were granted privileges primarily on the basis their profitability.

Economic credentialing also has serious legal implications for physicians. The federal Health Care Quality Improvement Act of 1986[4] grants peer reviewers immunity from damages caused by peer review—but only if the peer review decision was "based on the competence or professional conduct of an individual physician."[5] Peer review decisions based upon competitive matters such as "the physician's fees or... engaging in other competitive acts intended to solicit or retain business" or "any other matter that does not relate to the competence or professional conduct of a physician" do not qualify for the immunity.[6] If peer reviewers deny membership or privileges for competitive or financial reasons, therefore, they will lose the immunity of HCQIA and may also lose the peer review immunity granted by state law.

■ **How Physicians Should Respond to Economic Credentialing—** Economic credentialing violates the fundamental principle of the Joint Commission on Accreditation of Healthcare Organiza-

In Memoriam

1991

Lillian Marie Hoke, MD	October 25
Irwin Hubert Brown, MD	October 27
Harold Houston Jones, Jr., MD	October 27
Francis Ray First, Jr., MD	October 28
Robert W. Kahn, MD	October 30
Charles Hugh Wilson, MD	October 30
George Kellogg Stephens, MD	November 4
Edward M. Farris, MD	November 22
Weldon Keiller Haynie, MD	November 25
Samuel Richard Fryer, MD	November 30
William Thomas Snoddy, MD	December 3
Philip George Joseph, MD	December 20
Charles Patrick Kirkland, MD	December 24

1992

John Moore Campbell III, MD	January 24
Bruce Ratliff Hinson, MD	January 24
Louis Carroll Taylor, MD	February 3
Earl Russell Muntz, MD	February 4
Claude Marion Bloss, Jr., MD	February 24
Oliver James Hagg, MD	March 31
Francis Patrick Cawley, MD	April 17
Don Horatio O'Donoghue, MD	April 20
Billie Gene Henley, MD	April 24
Arlo Kenneth Cox, MD	April 27
Charles Victor Williams II, MD	May 1
Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11

Economic credentialing *(continued)*

tions, many state hospital licensing laws, most medical staff bylaws and AMA policy that credentialing decisions should be based upon the professional competence of the applicant. As patient advocate and the entity with overall responsibility for quality within the hospital, the medical staff should reject economic credentialing.

AMA policy strongly opposes economic credentialing.[7] Rejecting economic credentialing does not equate to a rejection of the need to maximize efficiency in health care delivery. Medical staffs have always been responsible to address utilization problems that affect quality of care through peer review. Medical staffs also should work with their hospitals to determine the appropriate educational uses of utilization and financial data.

To insure that economic credentialing does not infiltrate the medical staff bylaws, the staff should take two steps. First, it should review all proposed amendments closely, paying particular attention to requirements that physicians practice "efficiently," "in accordance with hospital resources" or "in accordance with all hospital policies." Other "buzz words" include *physician profiling, utilization screening* and similar terms. Second, the staff should retain its own attorney to review all proposed bylaw amendments and to assist the staff to develop a strategy for addressing efficiency while remaining the patient and quality advocate.

—Denise C. Andresen, JD
American Medical Association
Office of the General Counsel

Notes

1. AMA Council on Medical Service Report B (I-91).
2. See AMA Council on Medical Service Report B (I-91); see also Proposed Changes in Bylaws Upset Hospital's Medical Staff, *Modern Healthcare*, Aug. 10, 1992, at 18 (hospital's insistence on bylaws amendments that would authorize economic credentialing led surgeon to quit his practice at hospital).
3. See Report of California Medical Association Task Force on Exclusive Contracting and Economic Credentialing (1991) and Medical Society of the State of New York Policy Paper on Economic Credentialing and Exclusive Contracts (1992) (both documents compare utilization review that is related to quality of care with economic credentialing, and identify criteria that (i) are valid for quality assurance, (ii) may be valid for quality assurance and (iii) are totally invalid for quality assurance).
4. 42 U.S.C. // 11101 - 11152 (HCQIA).
5. Id. / 11151(9).
6. Id.
7. AMA Council on Medical Service Report B (I-gl); AMA Resolution 2 (A-91).

Originally printed in *FMA Today* (September/Octoher 1992)

Postscript: After the trial court rendered its decision in Rosenblum, Dr. Rosenblum reapplied for cardiac surgery privileges at TMRMC. His written contract to direct the open heart program had expired during the litigation, but he remained the director of the program and continued to carry out the same responsibilities as he had under the written contract. Surprisingly, TMRMC granted Dr. Rosenblum cardiac surgery privileges in August, 1992. The likely reason for TMRMC's capitulation is that the pivotal factor in the court's decision was the written contract with the competing hospital. Without that contract, the Rosenblum decision provides no basis for TMRMC to impose economic credentialing. J

Letters

■ Injury control and prevention

The following letter was recently sent to OSMA President James D. Funnell, MD, by Sue Makintubee, RN, MPH, Director of the Injury Epidemiology Division at OSDH. Enclosed was the letter from Dr. Claire V. Bloom, Acting Director of the National Center for Injury Prevention and Control at the Centers for Disease Control in Atlanta.

Dear Dr. Funnell:

Injuries are a major public health problem in Oklahoma. They are the third leading cause of death in Oklahoma, behind heart disease and cancer. Injuries account for 2000-2500 deaths per year, or 1 of every 14 deaths, and they are the leading cause of death among persons between 1 and 44 years of age. Furthermore, because injuries disproportionately affect children and young adults, they are the leading cause of years of potential life lost.

As outlined in the attached letter, the American Medical Association recently adopted a resolution to support injury control efforts in the United States. State and local medical societies are encouraged to work with health departments to make injury control a priority.

Since 1987, the Oklahoma State Department of Health has collected injury data and designed, implemented, and evaluated numerous prevention programs, including a smoke alarm giveaway, adolescent education programs, and low/no cost child car restraints and bicycle helmet campaigns. We would like to encourage support and collaboration from local physicians for these types of efforts. I would like to encourage you to print an announcement regarding the AMA's adoption of Resolution 410 in the *Journal of the Oklahoma State Medical Association,*

Millions Victimized by Family Members Every Year!

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Violence among family members has reached staggering proportions. Every year more than 2 million cases of child abuse and neglect are reported, between 2 and 4 million women are battered by their spouses, and between 700,000 and 1.1 million of the elderly population are abused.

The American Medical Association has formed a *National Coalition of Physicians Against Family Violence*. Through the *Coalition* the American Medical Association hopes to involve you in activities that address issues of child abuse, sexual assualt, domestic violence and elder abuse because you have the unique ability to identify the symptoms, first-hand. By joining the *National Coalition* you will be showing your concern about the effects of family violence and victimization, and will become a committed advocate within your community for the prevention of family violence.

Through the *Coalition* you will:

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Yes, include my name in the *Coalition's* membership

Name _____

Address _____

City/State/Zip _____ Telephone # _____

Specialty _____

Auxiliary Member ☐ Yes ☐ No Other _____

Area of interest within Family Violence: ☐ Child Abuse ☐ Sexual Assault ☐ Domestic Violence ☐ Elder Abuse ☐ Other

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Letters *(continued)*

and encourage physicians to work with local health departments and coalitions in support of injury control efforts. Together we can reduce deaths and disabilities from injuries in Oklahoma.

—Sue Makintubee, RN, MPH
Director, Injury Epidemiology Division
Oklahoma State Department of Health

Dear Ms. Makintubee:

I am writing to inform you of the adoption of Resolution 410 (A-92) by the American Medical Association (AMA) House of Delegates at their 1992 Annual Meeting. The significance of the commitment by the AMA is described by the four components of the Resolution:

1. The AMA supports the Centers for Disease Control's effort to conduct injury research; to develop a national program of surveillance and focused interventions to prevent injuries; and to evaluate the effectiveness of injury implementation strategies and prevention programs.
2. The AMA supports a Public Health Service public information campaign to inform the public and its policy makers of the injury problem and the potential for effective intervention.
3. The AMA supports the development of a National Center for Injury Control at CDC.
4. The AMA encourages state and local medical societies to work in conjunction with state and local health departments to make injury control a priority.

I am pleased to be able to inform you of the adoption of this Resolution and the support of the AMA. I hope that this will encourage you to continue to work with your state and local medical associations and societies to make injury control a priority.

—Claire V. Broome, MD
Acting Director
National Center for Injury Prevention and Control
Atlanta

■ More on spider bites and stun guns

To the Editor: Dr. Barrett is to be congratulated for developing a test for specific identification of Brown Recluse spider bites [JOURNAL, November 1992]. I cannot agree with the conclusion of danger from High Voltage Direct Current Multiple Shock by the technique I have outlined and have now used without a complication *from the procedure* in 498 cases with age range from 5 months to 93 years. A 50kv stun gun usually disables with a continuous 3-5 second shock - 150-250 Kv seconds. With auto ignition systems delivering 20kv-40kv (depending on type) the 5 minute shock to the lip would amount to 6-12 million volt seconds. I'm surprised he survived.

The other snake bite case has the perfect control with 4 punctures to one individual from one source at one time The different outcome for the three treated punctures compared to the untreated, added to my personal results (JOURNAL, July 1992) suggests the HVDC multiple shock treatment has merit.

—Carl D. Osborn, MD
Ada

DEATHS

John Graham, MD
1918 - 1992

John Graham, Idabel surgeon, died November 10, 1992, near Dallas, Tex. Born in Greenock, Scotland, Dr. Graham earned his medical degree at the University of Glasgow, Scotland, in 1954. He practiced in Houston and Richardson, Tex., before moving his practice to the Idabel–Broken Bow area in 1974. During World War II, Dr. Graham was a bombardier with the Royal Air Force.

John Frederick Kuhn, Jr., MD
1907 - 1992

OSMA Life Member John F. Kuhn, Jr., MD, died November 11, 1992, in Oklahoma City. Dr Kuhn was a retired obstetrician-gynecologist. He earned his medical degree at the University of Oklahoma School of Medicine in 1931 and later practiced at Oklahoma City's St. Anthony, Bone & Joint, and University hospitals. Dr Kuhn was also an associate professor of gynecology at the OU School of Medicine. During World War II, he served with the US armed forces for a total of 40 months, including 27 overseas.

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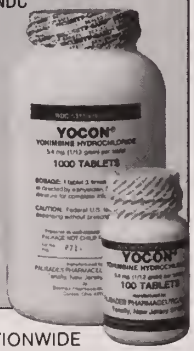
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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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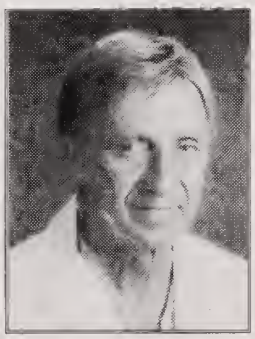
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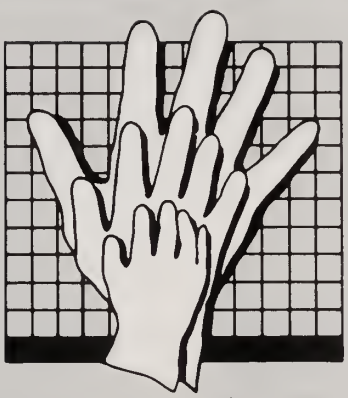
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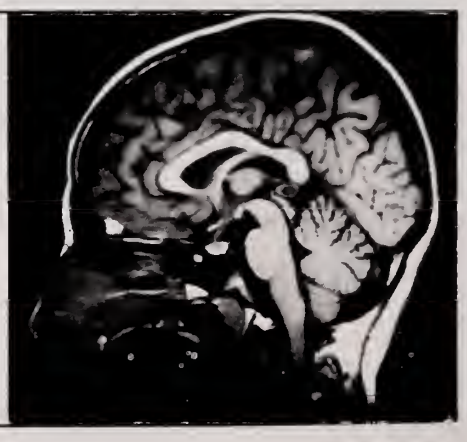
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Style

All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style.* An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

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Campaign Against Family Violence

When the AMA Auxiliary kicked off its Campaign Against Family Violence, its goal was to encourage state and county auxiliaries to educate the public about family violence, sponsor projects to support victims, and develop a list of community resources for physicians.

Family violence is a growing epidemic in the nation. It touches one-fourth of American families every single year, and its perpetrators and victims can be found anywhere. It is a problem shared by residents of the affluent suburbs, the inner city, and small-town America. It is a problem among white collar workers, blue collar workers, professionals, and laborers. It knows no boundaries among the rich, the poor, the young, and the old. It affects every race, nationality, and ethnic group.

In 1992, the child down the street may be one of the 100,000 children facing a brother or sister with a gun or knife in hand. Or your checkout clerk at the grocery store may be one of these women battered every 15 seconds. Or your neighbor may be one of the 900,000 older Americans abused by their children.

If those facts bother you, get involved in making sure these tragedies never happen—either to those you know or the millions you don't. The place to start is by learning what family violence is and what can be done.

How is family violence defined? Violence is the use of force by one family member with the intent to inflict injury—emotional or physical—or death upon another family member. The consequences of such violence are not just immediate and physical. For most victims, the resulting psychiatric and emotional problems seem never ending. Domestic violence is a pattern of control with one person dominating another through forced isolation, verbal abuse, threats, and intimidation.

The Oklahoma State Medical Association Auxiliary has adopted the Campaign Against Family Violence as their Health Promotions Project for this year. The state auxiliary has purchased a copy of the family violence video from the AMA Auxiliary and has made six copies for the county auxiliaries to use. Each county is encouraged to show the video and select a project appropriate for their county. The video, three minutes in length, features clips from children's cartoons, movies, television shows, and media reports, that graphically depict why violence in America has reached epidemic proportions. The audio portion of the tape combines the voices of news commentators reporting on the latest incidents of violence with the plaintive strains of a woman singing chilling words meant to arouse action on the part of the viewers: "Didn't anybody tell them that's not how it has to be?" If you are interested in viewing the video, please call Barbara Jett, State Health Promotions Chairman, at 405-755-3882.

Oklahoma County Auxiliary has had a meeting on family violence and battered children to educate their members on this growing epidemic. For their outreach in the community, the Oklahoma County Auxiliary is presenting a Teenage Health Symposium on January 28th, from 9:00 AM to 2:00 PM for the city area school children in grades 6, 7, and 8, at Metro Tech in OKC. These 200 children are selected by their school counselors. Other counties in Oklahoma have had programs on family violence for their members, school children, and community groups. Some counties have printed teen hot line numbers on pocket cards for junior and senior high school students.

The fact that no one is immune is why family violence has reached epidemic proportions in this country. We can control this epidemic only if we get involved. The first step we need to take is to learn what family violence is and what is being done to prevent it. There is abuse of the young, abuse of the elderly, and abuse of women.

People need to know that violence is not acceptable—not on television, not in our movies, not in our streets, and, especially, not in our homes. People need to know that we in the medical community are taking the lead in this fight because we are concerned, because we care, and because we believe we can make a difference. I urge you to join in this effort to help us make a difference. Whether the abuser or victim is a patient, friend, neighbor, or just a passing acquaintance, the odds are that family violence is taking a toll on someone you know.

—Barbara Jett, State Health Promotions Chair

Data collected from AMA and AMA Auxiliary facts on Family Violence

The Last Word

■ **This year the Journal celebrates its 85th** year as the official publication of the Oklahoma State Medical Association. The OSMA House of Delegates, at its May 1907 meeting in Shawnee, recommended the establishment of a medical journal, to be owned and controlled by the association and to be known as the Journal of the Oklahoma State Medical Association. The first issue was to be published June 1, 1908, and edited by the association's secretary, Dr. E.O. Barker of Guthrie, under the supervision of the Council. Dr. Barker was to be compensated $50 for the extra work involved in producing the issue. A year later, in Sulphur, the house approved the recommendation. Dr. Barker was elected editor and his salary was fixed at $25 a month after the first month, with a stenographer allowed when necessary. Shortly thereafter, in June 1908, Volume 1, Number 1 of the Journal of the Oklahoma State Medical Association was issued.

In order to have an official organ during the period between June 1, 1907, and June 1, 1908, the OSMA entered into a contract with the *Oklahoma Medical News-Journal,* an independent, privately owned publication. Its relationship with the OSMA officially ended with the publication of the first issue of the Journal of the Oklahoma State Medical Association.

■ **Finding a proper diagnostic test and cure** for interstitial cystitis is the newest goal of the University of Oklahoma Health Sciences Center in Oklahoma City. OUHSC recently was selected as the site of the National Institutes of Health's new Southwest Interstitial Cystitis Clinical Center, one of six such centers to be created through NIH grants. Dr. Johnny Roy, professor of urology, will serve as the center's director and principal investigator, with the assistance of Dr. Robert Hurst, professor of urology.

■ **The Fifth Annual Oklahoma Prevention** Convention will be held February 17-19 at the Doubletree Hotel in downtown Tulsa. "Youth Participation" is this year's theme. The convention is sponsored by the Oklahoma Department of Mental Health and Substance Abuse Services and coordinated by the OU Center for Child and Family Development. It will focus on wellness promotion and issues surrounding the prevention of alcohol and other drug use, and prevention of child abuse, domestic violence, teen pregnancy, suicide, and gang participation. Participants will be eligible for Continuing Education Units from the OU College of Continuing Education. For information contact Sue Carlson, 555 Constitution, Suite 221, Norman, OK 73037, or telephone (405) 325-1446 or 1-800-0772, ext. 1446.

■ **Patrick M. Morgan, MD, Oklahoma City in**ternist, has been elected to a three-year term on the Board of Directors of the Oklahoma Psychiatric Foundation.

■ **Nominations are still open for the OSMA's** Wyeth-Ayerst Physician Award for Community Service and the Donald J. Blair Friend of Medicine Award. Member physicians, county medical societies, and specialty societies may submit nominations with supporting material to Jay A. Gregory, MD, Chairman, OSMA Board of Trustees, 601 Northwest Expressway, Oklahoma City, OK 73118. Deadline for nominations is February 1, 1993. Winners will be selected by the board at its February meeting.

■ **Dr. Alfred W. Brann, Jr., Hobbs-Recknagel** professor and chairman of the OU Department of Pediatrics, is serving as interim director of the Center on Child Abuse and Neglect, recently established by the OU Health Sciences Center. The center's Medical Services Branch is under the direction of Dr. John H. Stuemky, associate professor of pediatrics and Dr. Nancy S. Inhofe, assistant professor of pediatrics. For more information about the center or its programs, call (405) 271-8858.

■ **Dr. Robert A. Wild, professor of obstetrics** and gynecology and adjunct associate professor of medicine-cardiology at OUHSC in Oklahoma City, has been appointed secretary-treasurer of the American Society of Preventive Cardiology. He was appointed at the annual meeting of the American Heart Association and will serve a one-year term. Dr. Wild is director of research in the OU Department of Obstetrics and Gynecology's Section of Reproductive Endocrinology and Infertility.

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As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransterases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 5 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, penpheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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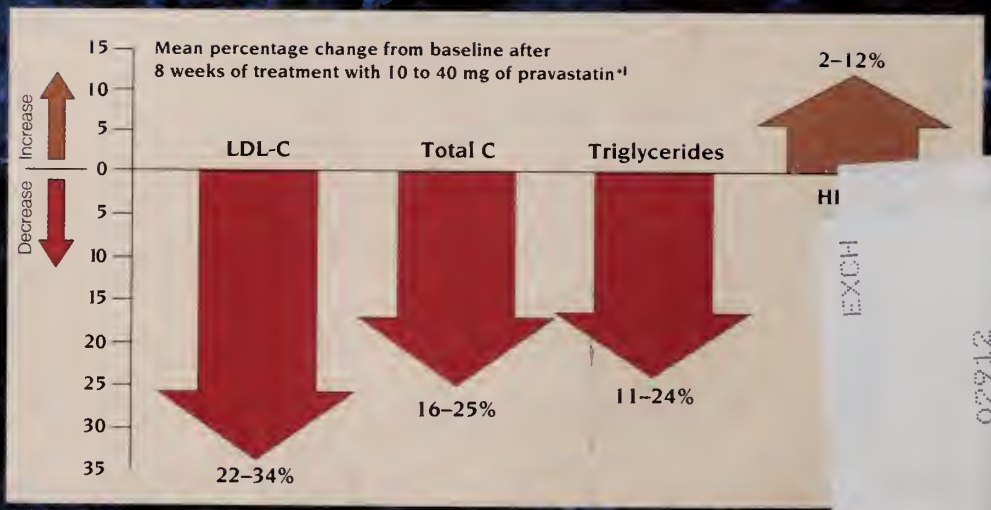
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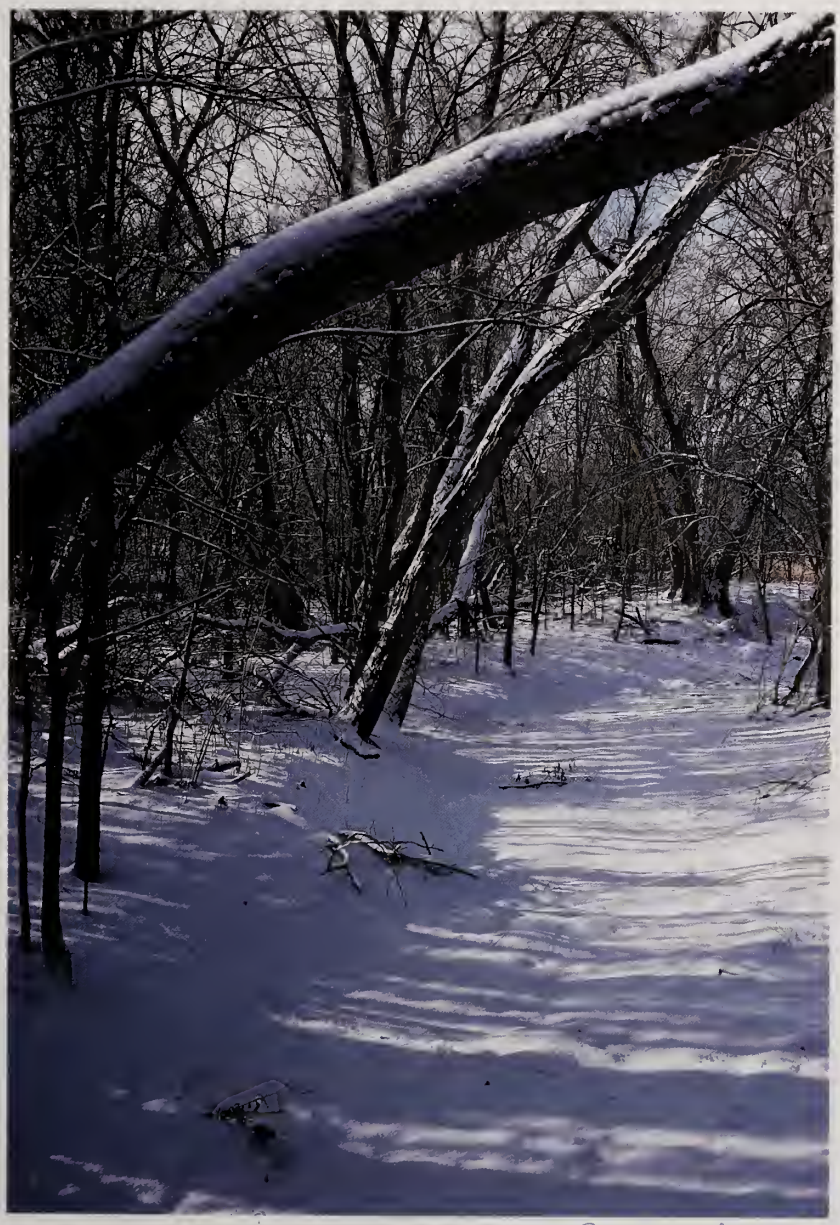
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EDITORIAL

Ray V. McIntyre, MD

Read the Bylaws!

In the troubled waters of today's medical economics, a disturbing subsurface whirlpool is increasingly detectable. Under the benign label "economic credentialing," this new riptide is a device of medical administrators to produce a profitable stream of patients through change in hospital staff bylaws policies.

Traditionally, hospital staff privileges have been contingent on academic qualifications and the delivery of good quality medical care, but some hospital administrators are now trying to make privileges contingent on the volume of patients admitted, the patient's ability to pay, or the quality of insurance coverage. Some of the proposed changes apply to the duration of the patient's hospital stay or the mix of patients' diseases. Usually these economic criteria are to be applied independently of patient outcome or the physician's quality of care. Most instances involve bylaw changes, although sometimes hospital policy changes are the projected control method. The new buzzword of this movement is "efficiency."

Hospital governing boards are entrapped in a typhoon of government programs and regulations, and beset by a hurricane of expensive technological changes, and are becoming frantic to develop new ways of increasing cash flow. Also, the current campaign to develop regionally integrated health systems capped by a managed care hospital is aimed toward the same end. These parallel administrative currents are moving our health care system toward a monopolistic, commercialized machine that is in danger of losing touch with the golden rule of patient care. The concepts of regionalization of franchised services developed by commercial entrepreneurs have penetrated into medical administration and are beginning to influence hospital interactions with patients and physicians. These notions of the hospital-patient relationship are beginning to resemble those of the fast food franchise with its patrons. Sick patients are being demoted to "customers."

Historically, hospitals arose in our society as hospices for the care of the dying, and in modern times have evolved into the site where complex medical care is made available to the seriously ill and injured. Both traditionally and presently, patient care is the hospital's reason for existence; if the commercialization of medicine is permitted to select those patients who will have hospital care, the basic relationship between hospitals and people will be dangerously altered.

While everyone knows that it takes money to buy a commodity, including health care, both physician and hospitals subsist, and may prosper, by the precept that the reason for being is to provide care, and that generating a cash flow is a secondary—although necessary—part of the activity.

This ideal must eventually affect "economic credentialing," as the hospital that cares more for the patient's financial status than the health outcome will lose both credibility and patients. The present movement among medical administrators away from the precept of quality patient care and toward the commercial concept of "market capture" is a signal of societal deterioration that physicians should not condone.

Physicians should be alert to proposed hospital bylaw and policy changes for economic factors that will affect adversely the quality of patient care. Physicians have a unique insight into the health care effects of economic phenomena, and this knowledge should be shared.

Ray V. McIntyre, M.D.

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James D. Funnell, MD

Welcome, My Friends, to 1993



Already a month old, 1993 promises to be exciting, revolutionary, and perhaps frightening. With President Clinton's administration in place, those of us in health care must not sit on our hands and watch as health care reforms are considered.

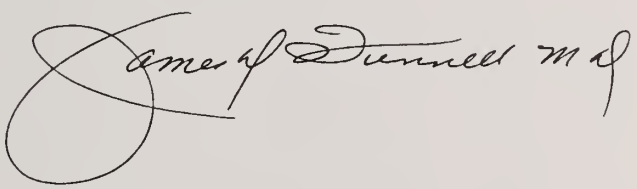
The presidents and executive directors of state medical associations received a special briefing from top officials of the American Medical Association during December's Interim AMA Meeting. We were overwhelmed with information on managed care, global fees, and the new buzzword from the Clinton administration: managed competition. Under managed competition, employees purchase insurance from providers–insurance cooperatives which compete against each other to provide the most efficient care to large pools of people.

The problem is that the Clinton administration has not released details of its health reform plan. The new President previously supported employer mandates and global budget, but today no one knows where we are going.

Insider newsletters speculate that in reality we will not see much in the way of health reform in the next few years because of the problems related to organization, cost, and legislative details. At the AMA Interim Meeting, one individual cautioned that many of these new plans, such as managed competition, are simply buzzwords or clichés much like Franklin Delano Roosevelt's New Deal, long on publicity but short on detail.

What other new "parameters" do we have? First and foremost, Jay A. Gregory, MD, Muskogee, continues to work religiously on practice parameters to update us on what the government has in mind. We will see substantial Medicaid reform in Oklahoma and, hopefully, changes in the way Medicaid is coded and how reimbursements are made. I also feel that there are some areas of tort reform, particularly for physicians performing charity services, which, through cooperation with the Oklahoma Bar Association, could occur during the year 1993. What a great opportunity it would be for physicians performing community services and running charitable clinics to have limited liability. As many of you are already aware, the Physician Liability Insurance Company (PLICO) has special day usage rates for physicians working in charitable clinics.

Again this year, let us work together to make the OSMA even stronger and more viable.



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SCIENTIFIC

Symposium on Antimicrobial Therapy
V. The Carbapenems and Monobactams

Ronald A. Greenfield, MD

This is the fifth article in Dr. Greenfield's series on antimicrobial therapy.

Within the last decade, two new classes of β-lactam antibiotics, carbapenems and monobactams, have become available. These warrant their own classification because of the fundamental differences in the chemical nucleus of these compounds, as discussed earlier in this symposium. These changes have produced antimicrobial agents that are quite distinct from other β-lactam antibiotics. At present there is only one available representative of each class. Imipenem (Primaxin®) is the sole carbapenem available. Aztreonam (Azactam®) is the sole monobactam available. Therefore we have the luxury of a rather short installment in this series. These two drugs will be discussed in turn. Finally, a soon-to-be-released carbacephem antimicrobial will be introduced.

Imipenem

Imipenem is the generic name for N-formimidoylthienamycin, a semisynthetic derivative of thienamycin, a natural antibiotic derived from *Streptomyces cattleya.*[1] Imipenem is marketed only as a fixed combination with cilastatin, i.e., imipenem-cilastatin. Cilastatin is not an antimicrobial agent; it has no antimicrobial activity. It is an inhibitor of a renal brush border enzyme, dehydropeptidase I. This enzyme (if not inhibited by cilastatin) hydrolyzes imipenem to a microbiologically inactive and nephrotoxic metabolite.[1] Imipenem-cilastatin (Primaxin®) will hereafter be referred to as imipenem for simplicity's sake.

Imipenem clearly has the broadest in vitro antimicrobial spectrum of any antimicrobial agent available for systemic therapy.[2,3] Here the activity of imipenem will be summarized by comparison to other agents; the implicit comparison is between the ratios of achievable serum concentrations and minimum inhibitory concentrations for 90% of organisms tested. Against Gram-positive cocci, the activity of imipenem is equal or superior to the penicillins for all organisms except enterococci. The activity of imipenem against enterococci is marginal. Methicillin resistant *Staphylococcus aureus* and coagulase-negative staphylococci (*S. epidermidis)* are generally resistant to imipenem. The activity of imipenem against aerobic Gram-negative cocci and bacilli, except for Pseudomonas species, is equal to or superior to third generation cephalosporins. Imipenem has good activity against *Pseudomonas aeruginosa; P. cepacia* and *Xanthomonas maltophilia* are generally resistant. Imipenem may be active against *P. aeruginosa* that are resistant to extended spectrum penicillins, ceftazidime, and aztreonam.[4] Imipenem has activity against anaerobic bacteria that is equivalent to or superior to clindamycin, metronidazole, cephamycins, and penicillin–β-lactamase inhibitor combinations. Imipenem has good in vitro activity against Nocardia. Mycoplasma, chlamydia, and mycobacteria are generally resistant.

The pharmacokinetics of imipenem are summarized

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as follows[5]: When imipenem is administered every 6 hours to normal volunteers, serum levels of the drug do not accumulate. Tissue penetration is good with the exception of penetration into cerebrospinal fluid, which has been variable. Imipenem is cleared completely by renal mechanisms; 1% of a dose is recoverable from bile, and fecal levels are generally immeasurably low. Dosage adjustment for renal insufficiency is mandatory. Dosages of imipenem above 500 mg q6h (25 mg/kg/day) should only be used in situations of marginal in vitro activity and then with extreme caution.

The most common adverse effects associated with imipenem therapy are infusion-site problems, nausea and vomiting, diarrhea, rash or drug fever, and seizures.[4] Seizures appear to occur in 1% to 3% of patients treated with imipenem, and identified risk factors are underlying neurologic disorder, renal insufficiency, and administration of excessive doses of imipenem.[6] Imipenem should be considered cross-reactive with penicillins and cephalosporins for immediate hypersensitivity reactions.[7]

The potential clinical usefulness of aztreonam is for treatment of serious aerobic Gram-negative bacillary infections.

What is the appropriate clinical use of imipenem? This is an expensive drug with epileptogenic potential in excess of that of other β-lactam antibiotics. Additionally, there is reason for concern about widespread use of imipenem leading to development of resistance and thereby limiting the usefulness of this "drug of last resort" β-lactam antibiotic. For these three reasons, imipenem is not the only antibiotic physicians need to know.

Imipenem is useful for *P. aeruginosa* infections resistant to other β-lactam antibiotics. As is true for *all* β-lactam antibiotics, imipenem should not be used alone for serious *P. aeruginosa* infections. Rather, it should be combined with an aminoglycoside, to prevent the emergence of resistance during therapy.[8] Imipenem is also a useful substitute for multidrug combination regimens; in this use it is both clinically and cost effective. One study has demonstrated superiority of imipenem as compared to clindamycin plus tobramycin for intra-abdominal infections.[9] This finding, if confirmed, has great clinical import. Imipenem should not be used for treatment of meningitis, due to its epileptogenic potential and lack of established efficacy.[4] I would support a more deductive approach to patient care than widespread empiric use of imipenem. Empiric use of imipenem for community-acquired infections is not recommended.

Additional carbapenem antimicrobial agents are currently in development. At present, there is no clear evidence of their superiority to imipenem.

Aztreonam

Monocyclic β-lactam antibiotics (monobactams) with weak antibacterial activity have been isolated from various soil bacteria, including Acinetobacter, Chromobacterium, Flexibacter, and Gluconobacter.[10] A single synthetic monobactam is commercially available at this time: aztreonam (Azactam®). Aztreonam's position among the β-lactam antibiotics is unique: this agent has activity essentially only against aerobic Gram-negative bacilli, with virtually *no* activity against Gram-positive bacteria or anaerobic bacteria.

Aztreonam has considerable activity against aerobic Gram-negative bacilli. Without belaboring details of the in vitro antimicrobial spectrum, some observations will be reviewed.[10] The activity of aztreonam rivals that of the aminoglycosides. Most *Enterobacteriaceae* are inhibited and killed by achievable concentrations. This includes bacteria of the genera Escherichia, Proteus, Providencia, Enterobacter, Citrobacter, Serratia, Klebsiella, Morganella, Salmonella, and Shigella. The activity of aztreonam against the *Enterobacteriaceae* generally equals or exceeds that of the third generation cephalosporins. Some organisms of this family that may be resistant to cephalosporins and aztreonam are *Citrobacter freundii, Enterobacter aerogenes,* and *Enterobacter cloacae.* Neisseria and Haemophilus strains are also generally inhibited. Aztreonam has inhibitory activity against ≥80% of strains of *Pseudomonas aeruginosa* in most studies. Some strains of *P. aeruginosa* may be inhibited but may not be killed (i.e., tolerant to the lethal effect).

Aztreonam is currently only available for parenteral administration; oral absorption is poor. Dosages used range from 0.5 gm q12h for urinary tract infections to 2 gm q6-8h for severe *P. aeruginosa* infections. Aztreonam is eliminated primarily by renal excretion; dosage modification is indicated in the presence of renal insufficiency. Aztreonam pharmacokinetics have been reviewed elsewhere.[11] Although preliminary data sug-

gest that aztreonam achieves therapeutic concentrations in cerebrospinal fluid of patients with meningitis,[12] there is little experience with aztreonam treatment of meningitis; therefore, this can not be recommended.

Aztreonam shares the favorable toxicity profile of the β-lactam family. There appear to be no unique toxicities associated with use of this agent. This agent does not appear to be cross-allergeneic with other β-lactam antibiotics.[7]

It is apparent that the potential clinical usefulness of aztreonam is for treatment of serious aerobic Gram-negative bacillary infections. The central question then becomes: in which situation(s) can and should aztreonam be used in place of aminoglycosides in patients with such infections? There is considerable evidence of the efficacy of aztreonam in treatment of a variety of Gram-negative bacillary infections due to susceptible organisms.[10] Organisms causing Gram-negative infections acquired in the community are likely to be sensitive to aztreonam, and the efficacy of empiric use of aztreonam as a component of empiric therapy for such patients (agents with Gram-positive and anaerobic activity are often also indicated) is amply documented.[13,14] Similarly, aztreonam appears a reasonable Gram-negative component for empiric therapy in the neutropenic host.[15] As with *all* β-lactam antibiotics, for treatment of serious *P. aeruginosa* infections, aztreonam should generally be combined with an aminoglycoside.

In summary, aztreonam is useful for many Gram-negative bacillary infections, and in many patients, can be substituted for an aminoglycoside. The toxicity of aztreonam is generally less than that of the aminoglycosides. However, aztreonam therapy costs more than aminoglycoside therapy, and its spectrum of activity is not quite as reliable against aerobic Gram-negative bacilli as that of the aminoglycosides. Certainly, in patients at risk for aminoglycoside toxicity, after documented in vitro susceptibility, it is reasonable to use aztreonam. If the cost of aminoglycoside monitoring and toxicity is included, the cost of aztreonam begins to appear more competitive.[16] In many community acquired infections, aztreonam is a reasonable alternative for Gram-negative therapy in patients at substantive risk for aminoglycoside toxicity. In many hospital-acquired infections, I would still prefer, empirically, the spectrum of activity of the aminoglycosides.

Additional monobactams are currently in development: examples are the parenteral agent carumonam and the oral agent tigemonam. More are likely to be developed.

Loracarbef

Well, if there are carba*pen*ems, could carba*ceph*ems be far behind? Obviously not. The carbacephems are synthetic β-lactam antimicrobials. The first of these, loracarbef (Lorabid®) has been approved by the U.S. Food and Drug Administration with a 1C rating (new molecular entity with little or no gain over existing therapies) for treatment of mild to moderate infections of the upper and lower respiratory tract, urinary tract infections, and skin and skin structure infections. Marketing in the U.S. is expected late in 1992. There is little published information about loracarbef at this time. It appears to have activity intermediate between cephalexin and cefuroxime, as a comparison on the scale of oral cephalosporins. A complete evaluation is not possible at this time.

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Methicillin-Resistant Staphylococcal Urinary Tract Infection Treated with Dicloxacillin

Camisa Stewart, MSIV, PA; Timothy S. Shaver, MD; D.J. Flournoy, PhD; Lula Smith, RN; Tonya Giessmann, PA-C; John A. Mohr, MD

Methicillin-resistant staphylococci (MRS), both coagulase positive and negative, account for over 20% of all hospital-acquired Gram positive infections. Twenty-five percent of all MRS carriers will have culturable MRS in the urine at some point in time. Since the only widely accepted treatment for these infections is intravenous vancomycin and because the penicillin are excreted in high concentrations in the urine, a study was done to evaluate the effectiveness of oral dicloxacillin in MRS urinary tract infections (UTIs).

Six patients with MRS UTIs (5 coagulase positive and 1 coagulase negative) were treated on an outpatient basis with 500 milligram (mg) of dicloxacillin four times a day for 10 days. All six patients responded clinically and microbiologically. Therefore, we propose that dicloxacillin be considered as a potentially suitable alternative for the treatment of methicillin resistant Staphylococcal urinary tract infection.

Methicillin-resistant staphylococci (MRS) were first reported in the early 1960s and became a major cause of nosocomial infections in Europe later in that decade. It wasn't until the late 1970s that MRS became a significant problem in the United States.[1,2] By the early 1980s, MRS were responsible for approximately 20% of all hospital-acquired Gram positive infections, second only to enterococci.[3,4] Twenty to thirty percent of the general population are permanently colonized with staphylococci and up to 3% of these are methicillin resistant. These are primarily patients who have been recently hospitalized or are in long-term care facilities. Twenty-five percent of all MRS carriers will have culturable MRS in the urine at some point in time.[5]

Fortunately, MRS urinary tract infections (UTIs) are less frequent. However, since the only widely accepted treatment for these infections is intravenous vancomycin and because the penicillin are excreted in high concentrations in the urine, a study was undertaken to evaluate the effectiveness of oral dicloxacillin in MRS urinary tract infections. The study involved six patients who were treated with oral dicloxacillin 500 mg four times a day for 10 days. The patients were evaluated daily by members of the hospital-based home care program nurses, physician assistants, and physicians.

Case 1

The patient is a 72-year-old white male with severe atherosclerotic peripheral vascular disease resulting in left above-the-knee amputation and right below-the-knee amputation, as well as congestive heart failure, chronic obstructive pulmonary disease, and bladder outlet obstruction. Because of the latter condition, the patient required intermittent self-catheterization. He was known to be colonized with MRS on the skin. On 7/17/90, surveillance laboratory values revealed a white blood cell count of 18,900 per cubic milliliter (ml^3). The patient complained of mild dysuria but was afebrile. A

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urinalysis revealed white blood cells too numerous to count, and cultures grew $>10^5$ colony-forming units per milliliter (CFU/ml) of *Staphylococcus epidermidis* resistant to oxacillin. The patient was placed on dicloxacillin 500 mg four times a day for 10 days. The patient's dysuria and leukocytosis resolved. Urine cultures submitted seven days after completion of the dicloxacillin were negative for urinary pathogens.

Cases 2 and 3

A 55-year-old white quadriplegic male with Type II diabetes mellitus, a seizure disorder, and indwelling Foley catheter who had been hospitalized repeatedly for urinary tract infections presented to the emergency room on 9/14/89 with fever, chills, and lower abdominal discomfort. The urine culture grew $>10^5$ CFU/ml of MRS, and the patient was treated with dicloxacillin 500 mg four times a day for 10 days. After 96 hours of therapy, the patient's signs and symptoms had resolved. Urine cultures 10 days following therapy were negative.

Fourteen months later the patient began to complain of fever, chills, and abdominal discomfort associated with cloudy urine. Urine cultures once again revealed MRS. The patient was started on the above regimen of dicloxacillin and his symptoms resolved within 48 hours. Urine cultures seven days after completion of the dicloxacillin were negative for MRS.

The cost relating to both toxicity and expense of hospitalization that accompanies the use of intravenous vancomycin must be kept in mind.

Case 4

An 82-year-old white female with chronic obstructive pulmonary disease, hypothyroidism, rheumatoid arthritis, and a recent hospitalization for pneumonia presented to the outpatient clinic with dysuria, frequency, and nocturia of 3 days' duration. Microscopic urinalysis showed 50-100 WBCs with clumps, 10-20 RBC, and positive nitrate. The cultures grew $>10^4$ CFU/ml of MRS. The patient was treated with oral dicloxacillin 500 mg four times a day for 10 days. The symptoms had abated by the fifth day of treatment, and repeat cultures seven days after completion of therapy were negative for MRS.

Case 5

A 77-year-old male with a history of Alzheimer's disease and Type II diabetes mellitus required inpatient admission on multiple occasions. One week after discharge, the patient was seen by hospital-based home care personnel. He was noted to have urinary incontinence and increased confusion. A urinalysis revealed pyuria and Gram positive bacteriuria. Urine culture was positive for $>10^5$ CFU/ml of MRS. A 10-day course of oral dicloxacillin 500 mg four times a day was instituted. One week after completion of therapy the patient was continent, his mental status had returned to baseline, and urine cultures were negative for MRS.

Case 6

A 76-year-old white female with Type II diabetes mellitus and recent hospitalization for an exacerbation of congestive heart failure was seen one week after discharge complaining of dysuria and frequency associated with fever and chills. Laboratory tests revealed leukocytosis of 12,500/ml[3] and the urine culture was positive for >105 CFU/ml of MRS. The patient was treated with a 10-day course of oral dicloxacillin. Repeat cultures seven days after completion of treatment were negative for pathogens.

Discussion

Vancomycin has been recommended as the drug of choice for the treatment of MRS infections.[6-9] Its mode of action consists of the inhibition of both cell wall and RNA synthesis.[9] Its use has the increased risk of both nephrotoxicity and ototoxicity as well as requiring intravenous administration necessitating hospitalization and blood level monitoring. The results of this study show that all six of our patients responded favorably both clinically and microbiologically to a 10-day course of oral dicloxacillin without significant side effects.

Dicloxacillin is a semisynthetic penicillinase-resistant penicillin of the isoxazolyl class. Of this group, dicloxacillin is the most effective antimicrobial agent against staphylococci (MICs ranging from 0.05 to 0.8 mg/ml) as opposed to oxacillin and cloxacillin.[10] Table 1 shows that approximately 40% of a dose of dicloxacillin is excreted in the urine and, although peak urinary levels have not been widely reported, cloxacillin which is 21% to 38% excreted in the urine attains peak concentrations of 410 mcg/ml to 1080 mcg/ml.[11]

Serum levels of dicloxacillin were not done because as early as 1955, Kass suggested that antimicrobial

activity in the bloodstream was not essential for effective treatment of urinary tract infections, but that inhibitory levels in the urine was all that was required to eradicate pathogens.[12] Further studies have shown that oral antibiotics were effective in treating patients with urinary tract infections when serum inhibitory activity was not detectable.[12,13]

For our patients, the MIC ranged from 78 mcg/ml to 156 mcg/ml, which is relatively high. Our laboratory determined the urinary concentrations of dicloxacillin exceeded 200 µg/ml. If we assume urinary concentrations of 410 mcg/ml to 1080 mcg/ml of dicloxacillin, we can easily exceed both the MIC and MBC of resistant staphylococci.

The cost relating to both toxicity and expense of hospitalization that accompanies the use of intravenous vancomycin must be kept in mind. Table 2 shows a comparison of direct cost for oral dicloxacillin versus intravenous vancomycin.

Because of the expense, toxicity, and need for hospitalization that accompany the use of intravenous vancomycin, we propose dicloxacillin be considered as a potentially suitable alternative for the eradication of MRS UTI.

Table 1. Serum and Urine Concentrations of Selected Antibiotics

Drug	Dose	Serum mcg/ml	Urine mcg/ml	% Dose Excreted
Penicillin	12 gm IV	16	4,000	80
Ampicillin	500 mg po	2.5-4	100-700	34
Methicillin	2 gm IV	72.4	—	66
Nafcillin	500 mg IV	11	—	11
Oxacillin	500 mg IV	43	—	22
Cloxacillin	500 mg po	7-14	410-1080	21-38
Dicloxacillin	500 mg po	1-14	—	40
Vancomycin	1 gm	20-50	800	80
Trimethoprim	1 tab (80 mg)	1-3	58-76	67
Sulfamethoxazole	40 mg (40 mg)	20-50	97	84.5

Table 2. Cost Comparison

Vancomycin		
1 gram intravenous every 12 hours x 10 days		$ 1,560.00
Hospitalization		$ 11,000.00
Peak/Trough levels (2 sets)		$ 184.00
	Total	$ 12,744.00
Dicloxacillin		
500 mg orally four times a day		$ 28.60
No drug levels needed		
No inpatient stay required		
	Total	$ 28.60

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SPECIAL

HIV and Hepatitis B Infections in Health Care Workers: History and Update

From the Oklahoma State Department of Health

National and Oklahoma guidelines for HIV- and HBV-infected health care workers are reviewed.

Health care workers (HCWs) have always been at some degree of risk of acquiring infections from their patients. The knowledge that thousands of HCWs have acquired hepatitis B virus (HBV) from patients, and that approximately 0.3% of needlesticks from human immunodeficiency virus (HIV)–infected source patients result in seroconversion, led to the development of universal precautions and the new Occupational Safety and Health Administration (OSHA) guidelines. The concept of universal precautions directs HCWs to treat every patient as though he or she might be infectious with some bloodborne pathogen; the OSHA guidelines mandate standards of infection control and the opportunity for hepatitis B vaccination. Although universal precautions have been successful in reducing the number of nosocomially acquired infections in HCWs through gloving and washing, they have been less successful in reducing the number of sharps injuries. Thus, the concern and risk of acquiring HIV from patient care remains.

The reverse risk, that of HIV transmission from a HCW to a patient, was only theoretical until the news that a Florida woman's HIV infection was acquired in a dentist's office. Until then, guidelines had been directed at protecting HCWs from acquiring infection during their work. Prompted by the uproar, in July 1991, the Centers for Disease Control (CDC) released its "Recommendations for Preventing Transmission of HIV and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures." (*MMWR*, July 12, 1991, Vol. 40, RR-8)

The CDC recommendations introduced the concept of *exposure-prone* invasive procedures, that is, those procedures with a recognized risk of contaminating a patient's tissues with blood from a HCW. The risk results from percutaneous injury to a HCW *inside* a patient, usually by digital palpation of a needle tip in a poorly visualized body cavity or the close proximity of fingers and sharp objects in a highly confined anatomic site. The concept of exposure-prone invasive procedures was developed from studies of surgeons and dentists who had transmitted HBV to their patients. In each case, the HCW was 'e' antigen positive, and dental work or deep abdominal or pelvic surgery was frequently involved. Other studies showed that in these anatomic sites, digital needle tip palpation and fingersticks are more likely to occur than with other surgeries. Placing vascular catheters, suturing lacerations, and almost any invasive office procedure are *not* considered exposure-prone because the needle position is always exactly known; if a needlestick did occur, gloves and pulling away would prevent blood transfer back to the patient. (The risk to the HCW would remain.) Procedures without sharps, such as dressing wounds, carry no risk of bloodborne pathogen transmission whatsoever if universal precautions are maintained.

The CDC recommendations suggested that: (1) test-

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ing of HCWs for HIV or HBV not be made mandatory, but that HCWs who perform exposure-prone procedures should know their HIV and HBV status; (2) universal precautions, proper disinfection, and sterilization of reusable devices are necessary; (3) HCWs abstain from patient care when open lesions or weeping dermatitis of the hands is present; (4) HCWs who do not perform exposure-prone invasive procedures and who comply with universal precautions should not have their practice restricted; and (5) any HCW infected with HIV or HBeAg-positive HBV should not perform exposure-prone invasive procedures unless they had sought council from a local expert review panel and followed their advice, including, at a minimum, notifying prospective patients of their HIV/HBV status before performing such procedures. The local expert review panels were to determine which procedures were exposure-prone.

The outcry of professional associations was immediate. Over 32 other "look back" studies involving over 15,000 patients of HIV-infected HCWs have failed to find a single case of transmission to their patients. In the best known study, a family doctor in Minnesota had continued to delivery babies vaginally, despite being HIV-positive and having open lesions on his hands due to *Mycobacterium marinum*. He saw 336 patients who underwent at least one examination with a digit in a body cavity, including 38 vaginal deliveries during which he wore only a single set of latex gloves. All but 10 of the patients were later found and consented to HIV testing; all were negative (Danila RN, MacDonald KL, Rhame FS, et. al. A look back investigation of an HIV infected physician. *N Engl J Med* 1991; 325:1406-1411). Although the Florida case shows that HCW-to-patient transmission can occur, it must be extremely rare. Although the exact facts of transmission are not clear, in the past, many dental offices did not rigidly enforce infection control procedures, although that is now changing.

A number of other controversies over the CDC recommendations exist, beside that of many restrictions for an unquantifiably low risk. First, it does not make scientific sense to equate HIV and HBV, because HBV is at least a hundred times more contagious than HIV, especially when 'e' antigen is present. Second, because no HIV transmission has been documented to occur during surgery, informing patients of a HCW's seropositivity is seen as unwarranted. It would certainly destroy all confidentiality and thus the HCW's practice, and therefore would decrease the willingness of HCWs to be tested or reported. Third, individual hospitals usually do not have the expertise to develop lists of exposure-prone procedures, even for HBV. Finally, when professional organizations were asked to help prepare standard lists of exposure-prone invasive procedures, they refused, citing the above factors, as well as that HBV transmission had decreased since the introduction of universal precautions, further decreasing the likelihood that even HBV would be transmitted during surgery.

The task force focused on coming up with a practical set of guidelines for working with infected HCWs and the medical community to try to assure a fair and confidential outcome for reported cases.

In response to this opposition, the CDC drafted a revised set of guidelines late in 1991, which was leaked to the press. However, the concept of not informing patients, even though the risk is vanishingly small, is politically unpopular; most polls show that Americans want all HCW *and* patients tested, regardless of cost or need. (The theoretical risk of a patient becoming infected during surgery has been estimated to be less than the chance of getting struck by lightning *twice.)* The HHS recently decided against releasing the revised guidelines.

Meanwhile, Congress passed Public Law 102-141, Section 633, which mandated that states certify that they are in compliance with existing CDC recommendations if they wish to continue receiving federal HIV/AIDS funding. Faced with this mandate, the inability of many hospitals to handle this issue, and the public demand for reassurance, the Oklahoma State Department of Health (OSDH) convened a task force to study this issue and recommend a set of guidelines for the state. The medical, osteopathic, dental, nursing, and hospital associations were invited to send members. The task force representatives realized that few, if any, infected HCWs would be reported if forced to follow CDC guidelines exactly, as is currently recommended by some of the licensing boards. Therefore, the task force focused on coming up with a practical set of guide-

lines for working with infected HCWs and the medical community to try to assure a fair and confidential outcome for reported cases. An analogy can be drawn with chemically impaired physicians; few were ever reported to the licensing board but many have been reported to the Impaired Physicians Committee, once it became known that there was a fair opportunity for confidentiality, treatment, and continuation of medical practice. The objective was to create a similar situation for the HIV/HBV-infected HCW. Guidelines were drafted, then sent to all major health care–related professional associations and licensing boards in the state of Oklahoma. Comments were reviewed, and the document was revised, presented to the Commissioner of Health, and accepted as a reasonable set of working guidelines; they have now been adopted by the Oklahoma State Board of Health.

The OSDH working guidelines are very similar, but not identical, to the CDC guidelines. They are similar in recommending that (1) universal testing of HCWs is not warranted but that voluntary testing be encouraged; (2) universal precautions and strict infection control guidelines, including proper disinfection and sterilization, be observed and taught in professional schools, and that ongoing training for these occur (all now mandated by OSHA); and (3) HCWs refrain from any invasive procedure when their hands have open lesions or weeping dermatitis. The guidelines also recommend that when an HIV/HBV-infected HCW is identified, he/she be reported to the HIV/STD Service of the OSDH, as is required for any HIV-infected person. An epidemiologist will then contact the HCW's physician to learn more about the HCW's practice. If the HCW may be performing exposure-prone invasive procedures and is HIV- or HBeAg-positive, a closed meeting of an advisory committee at OSDH will be called to review the case and to consider whether there is any reason to restrict the HCW's practice, or if monitoring is required. Hospitals will not need their own review boards, although they may certainly have them. The OSDH advisory panel will consist of the Commissioner of Health, the state epidemiologist, an infectious disease physician, OSDH legal counsel, and two representatives named by the HCW's professional organization who have the same specialty as the involved HCW. The infected HCW (or proxy), the HCW's physician, and counsel (if desired) will be invited. The proceedings will be strictly confidential.

The advisory committee will review the facts of the case and make recommendations. If the HCW plans to continue performing exposure-prone invasive procedures, someone at the involved hospital will need to ensure that proper infection control practices are being followed, that no invasive procedures are performed while there are open lesions or weeping dermatitis on the hands, and that the HCW's mental status does not deteriorate. The HCW's physician can certainly assist with this, but monitoring may require working with another surgeon or dentist at the same facility as the HCW. This will be decided by the committee, as well as the contact person, with input from the HCW. If the HCW remains free of hand lesions or weeping dermatitis, does not develop dementia, and strictly follows infection control practices, including double gloving during invasive procedures, the HCW can continue to practice.

If the [infected] HCW remains free of hand lesions or weeping dermatitis, does not develop dementia, and strictly follows infection control practices, including double gloving during invasive procedures, the HCW can continue to practice.

It will be more difficult to monitor infected HCWs who are performing exposure-prone invasive procedures, especially in solo private practices, as often occurs with dentists. However, with the new OSHA guidelines, some regular monitoring and inspection could occur without raising suspicion unnecessarily. Given the current misconceptions about HIV and the discrimination towards infected persons, the committee may even need to assume an advocate's role to allow the HCW to continue to practice.

Legislation that will allow the guidelines to work as intended was incorporated into HB 2214, which became law in September 1992. Two specific legal provisions were necessary: first, assurance was needed that any meetings would not be subject to the Open Records Act; and second, OSDH had to be allowed an exemption to the confidentiality statute so that it could potentially report HCWs who perform exposure-prone procedures to others who would monitor their infection control practices and/or health status. Reporting can also occur to the licensing board in the event that

an HCW is unwilling to comply with the recommendations of the advisory committee, although we envision this as a last resort that will be little used, much as occurs with the Impaired Physician Committee.

The OSDH guidelines are untested and may require modification as experience accumulates. However, these guidelines are working guidelines and provide a good starting point: a hospital will not necessarily have to set up its own HIV committee to review infected HCWs; physicians caring for infected HCWs who are still practicing can refer these cases to the advisory council without having to shoulder the responsibility for evaluation of their practice; confidentiality is maintained; and in most cases the HCW will be able to continue his/her practice intact. The recent report of the National Commission on AIDS, "Preventing HIV Transmission in Health Care Settings," which followed much of the same reasoning, came to conclusions very similar to the OSDH guidelines. At the annual OSMA meeting, the House of Delegates also endorsed this approach by recommending that the Oklahoma Board of Medical Licensure and Supervision replace its rule with a statement that infected physicians should seek consultation from the OSDH Advisory Committee as to necessary restrictions or precautions, if any. The guidelines should prove to be a reasonable option for infected HCWs. A copy of "Guidelines for HIV Infected Health Care Workers," or the parallel document on HBV, can be obtained from the OSMA or the OSDH. Although some are skeptical that an HIV-infected surgeon would ever be reported to the OSDH under this system, the increasing number of HIV-infected persons virtually guarantees that these situations will arise. These guidelines are a start towards meeting that need. We would be happy to work with any interested physicians to improve these guidelines, and welcome your input.

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Decisions Regarding Services for the Frail Elderly

M. A. Bernard, MD; L. Morgan, MD

This article reviews recent literature regarding geriatric assessment and options for care, with an emphasis upon practical suggestions for the primary care physician in Oklahoma. Data gathering was based upon a Medline search of the medical literature, as well as the authors' experience as practicing geriatricians. The article summarizes standardized geriatric assessment of the frail elderly. There is also a description of options for care (with the exception of nursing home care): adult day care, rehabilitation, and home care. There are a number of options for care of the frail elderly. The challenge for the primary care physician is appropriately selecting from among these options.

The graying of America is not just a cliché. In 1990, 12.5% of the U.S. population was over sixty-five years of age, and this percentage is expected to increase to 22.2% by 2050. The old old (those 85 years and older) is the fastest growing segment of the elderly as well as the general population. In 1990, the old old made up 1.3% of the total population and is projected to increase to 5.1% by 2050. This accelerated growth rate of the elderly, especially the old old, is creating an enormous challenge for the health care system in general and the health care providers specifically. It will be the goal of this article to review for the primary care physician appropriate assessment, and alternatives for care (with the exception of nursing homes), of the frail elderly.

Assessment of the Frail Elderly

With increasing age, there is an increase in chronic conditions, multiple comorbidities, dementia, and overall decline in physical functioning. The result is the creation of a segment of the elderly patient population, the frail elderly, who challenge the ingenuity of the health care system and providers alike. Who are the frail elderly? Buchner and Wagner define *frailty* as the state of reduced physiologic reserve associated with increased susceptibility to disability.[1] This definition has the problem of including patients who are still fully functional. There are several other definitions of frailty, each with its limitation(s). Speechly and Tinetti identified nine variables using factor analysis to characterize frailty.[2] These variables can be grouped into three subclasses. The first, predictors of future loss of physiologic reserve, includes age >80, depression, sedative medication use, and sedentary life style. The second group is characterized by indicators of loss that consist of decreased muscle strength in the shoulder or knee, and visual loss. The third group, clinical measures of disability, includes measurement of gait, balance, and lower extremity disability. All of these factors are associated with increased risk for institutionalization, morbidity, and mortality.

Clearly, frail elderly patients are at extreme risk for poor health care outcomes. Part of this risk is indigenous to the patient (poor functional state). How-

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ever, some of this risk results from inadequate assessment of the patient's functional state. The elderly are well known for failure to self-report symptoms. Also, routine clinical assessment may not identify the true level of functioning in the elderly. When patients do not self-report and clinical assessment is unrevealing, it is necessary to employ different strategies. Some providers may not have knowledge of these strategies. Nevertheless, if functional status is not adequately determined, appropriate social and medical interventions can not be employed.

According to literature reports, many health care providers are inadequately trained to provide quality health care to the rapidly growing elderly population, especially the frail elderly.[3] However, the growing elderly population cannot wait until medical schools can produce adequate numbers of geriatricians. It is important, therefore, that primary care physicians be taught to care for the elderly. The major points to consider are: (1) routine clinical assessment may be inadequate for this age group; (2) assessment instruments may be necessary to provide appropriate evaluations; (3) interdisciplinary teams may be needed to evaluate patients and provide needed services; and (4) provision of social services is just as important as the delivery of medical care in the elderly. Therefore, an essential part of this training should be the use of assessment instruments and interdisciplinary teams.

Assessment of the elderly should focus on at least four areas: physical, psychological, cognitive, and social functioning. Assessment of physical functioning should begin with a thorough physical examination, including observing patients as they perform tasks. During this period, the clinician should be able to evaluate the patient's gait, balance and muscle strength, endurance (looking for dyspnea, fatigue, chest pain, etc.), and ability to perform basic activities of daily living. However, if the clinician cannot afford the investment of time, there are other options. These options include training office personnel to administer standard assessment instruments (Tables 1 and 2), consulting occupational and physical therapists, and having the patient assessed at a geriatric assessment unit.

There are several standard instruments that are commonly used to assess physical functioning (basic activities of daily living, BADL, self-care). These include the Barthel Index,[4] Katz Index,[5] and the Kenny Self-Care Evaluation.[6]

The Barthel Index is a numerical scale that measures percentage of functional independence. Ten functional areas are evaluated: feeding, wheelchair/bed transfer, grooming, toilet transfers and use, bathing, walking or using a wheelchair, using stairs, dressing, and continence of bowel and bladder. The scores can range from zero (total dependence) to 100 (total independence).

The Katz Index uses an ordinal scale to measure six functions: bathing, dressing, toileting, transferring, continence, and feeding. Scoring identifies three levels of function: performs independently, performs with help, or unable to perform. It has good reliability and validity. It provides a good measure of the amount of assistance needed for a particular patient.

The Kenny Self-Care Scale evaluates six functional

Table 1. Deficiencies in Basic Activities of Daily Living (BADLs) and Appropriate Consultants

BADLs Deficit	Physical Therapy	Occupational Therapy	Speech
Eating	No	Yes	Yes
Hygiene	No	Yes	No
Dressing	No	Yes	No
Toileting	No	Yes	No
Ambulation	Yes	No	No
Gait	Yes	No	No
Balance	Yes	No	No
Transfers	Yes	No	No
Bed	Yes	No	No
Wheelchair	Yes	No	No
Communication	No	No	Yes

Table 2. Deficiencies in Instrumental Activities of Daily Living (IADLs) and Possible Solutions

IADLs Deficit	Needed Assistance To Live Alone	Remedy
House cleaning	Maid service	Homemaker service
Laundry	Laundry services	Homemaker service
Cooking	Food services	Meals on Wheels, etc.
Managing money	Delegated money manager	Power of attorney
Managing telephone	Should not live alone	Sitter, day care, etc.
Accessing	Transportation service	Taxi, family, & other assistance
Exiting residence alone	Should not live alone	Sitter, day care, etc.
Managing medications	Family or friend	Pill box, reminders
Grocery shopping	Family or friend	Surrogate shopper
		Retirement village with assisted living apartments

areas containing 17 items, including bed transfer, locomotion, dressing, personal hygiene, and feeding. The scores in each category range from zero (0) for dependent to four (4) for independent functioning. It was developed to evaluate the effects of therapy on hospitalized patients.

Basic activities of daily living assessment can determine a person's ability for self-care, whereas instrumental activities of daily living assessment can determine whether a patient can live alone with or without supportive services (Table 2). Strict requisites for living alone are mobility, ability to manage the telephone, good judgment, and the ability to exit the residence in case of emergency.

Psychological assessment instruments are used to assess cognitive function, dementia, and mood disorders. The Folstein test for cognitive status is highly recommended for primary care physicians.[7] It is easy to use, reliable, and requires a short time to complete. Instruments available for mood disorders are the Geriatric Depression Scale,[8] and the Hamilton Rating Scale[9] for anxiety. There are several scales for assessing dementia. However, they are not very beneficial for the primary care physician.

Adequate assessment of the geriatric patient, coupled with appropriate allocation of resources, can increase the amount of time patients can stay in their home before going to long-term care facilities. In addition, it can reduce the numbers of patients living alone who do not have the functional skills to do so. These individuals are at risk for falls, malnutrition, and other adverse outcomes.

Alternatives for Care of the Frail Elderly

Once a frail elderly individual has been identified using standard assessment tools, what are the alternatives for care, other than nursing home placement? Alternatives include adult day care, inpatient or outpatient rehabilitation (with the aim of improving the individual's level of function), and home care.

Adult Day Care. Adult day care in the state of Oklahoma was extensively covered in a recent issue of the JOURNAL OF THE OKLAHOMA STATE MEDICAL ASSOCIATION.[10] It should be emphasized that adult day care ranges from simple custodial care to full adult day hospitalization. The United Kingdom has employed varying models of adult day care for several decades. The

Table 3. Adult Day Care — U.S., 1986

	U.S.	vs	South
Urban (%)	78.1		72.0
Rural (%)	21.9		18.0
Private for profit (%)	9.9		7.7
Private not for profit (%)	70.2		66.4
Public (%)	19.8		25.9
Licensed (%)	57.6		79.3
Years in operation			
X	7.5		8.1
SD	5.9		4.3
Training program (%)	78.5		82.3
Formal training (%)	41.6		53.5*
Average hrs open	7.8		7.7
SD	2.5		2.4
Daily attendance	19.5		22.3
SD	17.5		20.6
Daily capacity	23.9		27.0
Average age	72.2		67.8
SD	11.0		14.9
Clients/core staff	10.1		10.2
Clients/staff	8.8		8.8
Attending clients/core staff	6.4		6.8
ADC's/100,000 elders	13.4		11.9
NH beds/100,000 elders	4737		4,698

*p<.01

The above is based upon a national census survey of 1,347 ADC centers, yielding 974 usable responses (72.3%), as reported by Harder et al, *Milbank Quarterly* 1986;64:414-441.[14]

Table 4. Medicare Criteria for Rehabilitation Hospital Admission

A primary problem in at least two of the following areas:

A. **Self-Care Activities** — Includes drink/feed, dress upper/lower, brace/prosthesis, groom, wash, bathe, perineal care.

B. **Mobility Activities** — Includes transfer chair/toilet/tub or shower, walk, stairs, wheelchair.

C. **Bladder/Bowel Continence** — Includes use of external device, maintenance of a voiding or excretion pattern or frequent accidents.

D. **Unstable Neurologic Disorder** — (Spinal cord or brain trauma) — Patient requires medical/nursing attention at least daily in addition to one of the above.

E. **Pain** — Pain behavior is such that it limits active motion or functional use to a marked degree.

F. **Perceptual, Cognitive or Communication Function** — Includes orientation, depth or distance perception, attention span, memory and aphasia with major receptive or expressive dysfunction.

G. **Acquired Secondary Complication** which may intensify sequelae such as contractures, decubiti, urinary tract infections, or increased spasticity; and the patient needs education in the proper management of his/her condition in order to avoid such complications.

United States experience is less extensive, and primarily focused on custodial care. Adult day care is defined as a community-based group program that is designed to meet the needs of functionally impaired adults through an individual plan of care, with a variety of health, social, and related support services, in a protective setting during any part of a day, but for less than 24 hours.[11] A 1986 survey of adult day care in the United States revealed findings as noted in Table 3.[12]

Legislation is under consideration in Congress and at the state level for funding of adult day care. Payment for services is presently via Title 20 (social services block grant monies) or private funds, with a few third party payers recognizing the benefits of adult day care. Prior studies of adult day care (ADC) did not find that it supplanted other forms of care;[13] it simply supplemented such. However, it can be postulated that in properly selected frail elderly, cost effectiveness of ADC may be demonstrated.[14] It appears empirically evident that, in the case where there is no responsible adult to care for a frail elder during the day, ADC is an option to consider.

The greatest limitation to care in the home is the limited payment available.

Full medical care/adult day *health* care (ADHC) is a common form of care in the United Kingdom, with this configuration much less common in the U.S.[15] There are questions regarding the effectiveness of this intervention versus routine care (with exemplary home care services) in improving quality of life and functional status.[16] There are also questions regarding cost savings with this extensive intervention.[17-21] There is an ongoing evaluation of ADHC within the Veterans Administration system. The results of that study are pending.[22]

Rehabilitation. Rehabilitation is an alternative to consider in the debilitated elderly who have had a recent decline in functional status—whether due to hip fracture, knee replacement, stroke, or generalized deconditioning due to severe illness. In studies which have evaluated the effect of geriatric assessment, only those assessment units with a rehabilitation component have been able to demonstrate improvement in mortality.[23-25] Criteria for admission are in Table 4.

Reimbursement for the admission will be by Medicare, Medicaid, or third party payer. DRGs have yet to influence inpatient rehabilitation, but it is anticipated that in the years to come, prospective payment will apply in this area as well. Outpatient rehabilitation is a little more difficult to obtain, unless associated with an inpatient stay. Table 5 shows a list of rehabilitation facilities within the state.

Home Care. Home care is the final option, other than nursing home care, for the frail elderly. There are several configurations for care, generally based upon a case manager of community services. Eligible veterans may take advantage of Hospital-Based Home Care Units, which have been found to be effective in the VA system.[26] The greatest limitation to care in the home is the limited payment available. Medicare covers home care for a brief period after an acute-care hospitalization. Medicaid, some third party payers, and the individual's private funds make up the remaining gap in payment. The local branch of the Areawide Aging Agency (AAA) is the most effective means of locating resources in a particular community to facilitate home care of the frail elderly. The AAA annually distributes the Senior Survival Kit, an invaluable resource in locating services for elders. Table 6 lists information for each AAA office in Oklahoma. The number to call in order to receive the Senior Survival Kit is (405) 943-4344.

Summary

The care of the frail elderly will become a progressive challenge in the decades to come. There are presently validated and standardized measures for assessing the frail elderly, as well as a number of options for their care. The challenge for the physician will be the proper selection of assessment instruments and care options.

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(continued)

Table 5. Section for Rehabilitation Hospitals and Programs*
Membership Listing 1992
Oklahoma Region 4

City	Hospital	Designated Rep.
Broken Arrow	Broken Arrow Medical Center 3000 South Elm Place Broken Arrow, OK 74012	Bruce Switzer Administrator 918-455-3535
Lawton	Comanche County Memorial Hospital 3401 Gore Boulevard Box 129 Lawton, OK 73505	Randy Curry President 405-355-8620
Muskogee	Muskogee Regional Medical Center 300 Edna M. Rockefeller Drive Muskogee, OK 74401	James F. Grocholski Admin. Assistant, Rehab. Services 918-682-5501
Oklahoma City	Baptist Medical Center of Oklahoma 3300 NW Expressway Oklahoma City, OK 73112	Ann Baumgarten Director, Patient Care Services 405-949-3964
Oklahoma City	Deaconess Hospital 5501 North Portland Avenue Oklahoma City, OK	Maurice Robison, R.N. Nursing Education Coordinator 405-946-5581
Oklahoma City	Oklahoma Medical Center O'Donoghue Rehabilitation Institute 1122 N.E. 13th Oklahoma City, OK 73104	Karen Mumina Administrator 405-271-6955
Oklahoma City	Oklahoma Neurosurgical Institute St. Anthony Hospital 1211 N. Shartel, Suite 300 Oklahoma City, OK 73103	Pamela Troup Executive Director 405-231-8900
Oklahoma City	Presbyterian Hospital N.E. 13th Street at Lincoln Blvd. Oklahoma City, OK 73104	David Dunlap Administrator 405-271-5100
Oklahoma City	Veterans Administration Medical Center 921 N.E. 13th Street Oklahoma City, OK 73104	Walter Whitcomb, M.D. Director/Physical Medicine & Rehab. 405-272-9876
Tulsa	Hillcrest Medical Center (Kaiser Rehabilitation Center) 12th & Utica Tulsa, OK 74104	John C. Goldthorpe President 918-560-5798
Tulsa	St. John Medical Center 1923 S. Utica Tulsa, OK 74104	Charles Anderson Director, Rehab. Services 918-744-2350
Tulsa	Tulsa Regional Medical Center 744 West Ninth Street Tulsa, OK 74127	James M. MacCallum President 918-587-2561
Vinita	Craig General Hospital 735 North Foreman Street Box 326 Vinita, OK 74301	Joe Gunn Administrator 918-256-7551

*This list is not exhaustive, but represents the most recent membership listing for this national organization (840 N. Lake Shore Drive, Chicago, Illinois, 60611 — 312/280-6000).

Table 6. Oklahoma Area Agencies on Aging

Area #	Name	Counties Covered	Administrator/Address/Phone
8	Areawide Aging Agency	Canadian, Cleveland Logan, Oklahoma	Don Hudman 3200 N.W. 48th, Suite 202 OKC, OK 73112 405-942-8500
1	Grand Gateway Economic Development AAA	Craig, Delaware, Mayes Nowata, Ottawa, Rogers Washington	Judy Branscum 320 S. Wilson, P.O. Box 330 Vinita, OK 74301 918-256-6478
2	EODD AAA	Adair, Cherokee McIntosh, Muskogee Okmulgee, Sequoyah Wagoner	Carolyn Pankey First National Sever's Bldg. 215 N. State Street, Suite 408 Muskogee, OK 74402-1367 918-682-7891
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11	OEDA AAA	Beaver, Cimarron, Dewey Ellis, Harper, Texas Woods, Woodward	Richard Adams 330 Douglas Avenue P.O. Box 668 Beaver, OK 73932 405-625-4531

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The Authors

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Leonard Morgan, MD, is an assistant professor in the Department of Family Medicine at the University of Oklahoma College of Medicine in Oklahoma City. He has a private practice in family medicine and attends geriatric patients in the Geriatric Continuity Center at O'Donoghue Rehabilitation Instituite.

— OFFICIAL CALL —

The House of Delegates of the OKLAHOMA STATE MEDICAL ASSOCIATION

WILL CONDUCT

ITS

87th ANNUAL MEETING

AT THE

ADAM'S MARK HOTEL TULSA

APRIL 23 THROUGH 25, 1993

Opening Session: 9 a.m., Friday, April 23
Closing Session: 9 a.m., Sunday, April 25

All members, delegates, alternate delegates, and county society officials are encouraged and urged to attend. Business to be brought before the House of Delegates must be submitted by March 23, 1993. All items of business will be debated in open reference committee hearings on April 23, 1993.

Any member of the association may submit business for consideration by the House of Delegates. For help in preparing information for submission, please contact OSMA headquarters, 601 Northwest Expressway, Oklahoma City, OK 73118, 405-843-9571 or 1-800-522-9452.

Larry Long, MD
Speaker of the House

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News

Nashville hosts 20th national assembly meeting of AMA-HMSS

The Twentieth Assembly Meeting of the American Medical Association-Hospital Medical Staff Section (AMA-HMSS) was held December 3-7, 1992, at the Opryland Hotel, Nashville, Tenn. There were 393 credentialed representatives in attendance at the meeting.

The AMA-HMSS considered 41 resolutions and 13 HMSS Governing Council Reports. The Assembly actions included:

Resolutions

13 Resolutions Adopted
6 Governing Council/Board/Council Reports Supported in Lieu of a Resolution
7 Resolutions Referred to the Governing Council
14 Resolutions Not Adopted
1 Resolution No Action

Governing Council Reports

12 Reports Adopted
1 Report Filed

Six resolutions were forwarded to the AMA House of Delegates for consideration at the 1992 Interim Meeting. In addition, the House considered 16 HMSS resolutions which were transmitted after the 1992 Annual Assembly Meeting.

The House of Delegates adopted 14 HMSS resolutions, adopted 3 Board of Trustees or Council reports in lieu of HMSS resolutions, and referred four resolutions to the Board of Trustees; one resolution was not adopted.

Oklahoma physicians attending the AMA-HMSS were: Joel Anderson, Jr., MD, Okmulgee; William O. Coleman, MD, Harold Masters, MD, and Clarence Robison, Jr., MD, Oklahoma City; Gordon Lantz, MD, and James R. Leach, MD, Tulsa; and Yale Parkhurst, MD, Weleetka.

On Thursday evening, December 3, an information exchange featured an analysis of the recent presidential and congressional elections by two political experts: Mr. Ed Goeass, Republican, and Mr. Tom King, Democrat.

The HMSS Education Program on Friday, December 4, was in two parts:

1. A "Futurist," Mr. Paul Keckley, outlined his predictions of health care in the year 2000. A "Reactor Panel" of AMA's Nancy Dickey, MD, and Howard Land, MD, challenged some predictions, agreed with some, and stimulated comments and serious questions from the HMSS representatives.

2. Physician/Hospital Organization (PHO) models for the future was presented by James Bentley, PhD, executive director of the American Hospital Association. Ronald Bangasser, MD, discussed a working PHO in California, and Mr. Ed Hirshfeld, AMA associate general counsel, outlined some of the legal concerns, including potential FTC problems.

The information exchange and the education programs are clearly highlights of the AMA-HMSS Assembly Meeting. However, the reference committees and the general assembly are where the resolutions and reports are debated—just as in the AMA House of Delegates.

A summary of the actions of the AMA-HMSS Assembly as well as the AMA-HOD is then mailed to each Oklahoma HMSS Representative attending the meeting and they, in turn, are encouraged to share this information with their medical staff.

Questions regarding the I-92 AMA-HMSS meeting should be directed to your medical staff representative.

Oklahoma hospital medical staffs are also encouraged to send their representatives to the Annual Meeting of the OSMA-HMSS in April 1993.

—William O. Coleman, MD
Chairman, OSMA-HMSS

HEALTH DEPARTMENT

Over 35? Illnesses related to smoking cost you $694 in '89

In November 1992, the Health Education and Information Service (HEIS) of the Oklahoma State Department of Health began to compile smoking-attributable disease impact information for Oklahoma. HEIS used the Smoking Attributable Mortality, Morbidity, and Economic Costs (SAMMEC 2.1) software and data provided to states by the Centers for Disease Control and Prevention, Office on Smoking and Health.

SAMMEC uses mortality data, economic cost data, and smoking prevalence data for large populations to make calculations that assess the health and economic consequences of cigarette smoking appropriate to the population. These estimates are developed in a public health context in which a value is placed on living healthfully to full life expectancy, and cigarette smoking is perceived as a threat to the collective health of society.

For 1989, the most recent year for which all data sources are available, HEIS estimates that smoking-related illnesses in Oklahoma cost more than $1 billion. Costs for persons age 35 and older were divided into three categories: direct health care, or medical costs; indirect mortality, or death, costs; and indirect morbidity, or illness, costs.

Direct health care costs, or medical costs, are the costs associated with the prevention, detection, treatment, and rehabilitation of persons with smoking-related diseases. Direct health care costs include expenditures for hospitalization, outpatient clinical care, nursing home and home health care, services of primary physicians and specialists, services of non-physician health practitioners, and medication. The distribution of smoking-attributable direct medical care costs in 1989 was:

Hospital care (68.7%)	$140,167,731
Physician fees (13.2%)	26,950,044
Nursing home care (11.2%)	22,879,340
Medication (6.5%)	13,263,985
Other prof. services (.4%)	810,161
Total	**$204,071,261**

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Smoking costs *(continued)*

Indirect mortality costs, also called costs due to death, are the estimated lost income and productivity for persons who die prematurely from smoking-attributable causes. Indirect mortality costs for 1989 are estimated at $709,622,169. Indirect morbidity costs, or the lost earnings and productivity of persons disabled by smoking-related chronic diseases in 1989 are estimated at $88,827,097. The losses, measured by wages, salaries and supplements, include days lost from work among the currently employed, persons unable to work because of illness or disability, persons institutionalized for health reasons, and the value attributed to housekeeping services of persons who are unable to keep house because of smoking-related illness or disability.

Smoking-attributable costs for men were almost three times the costs for women, with males accounting for nearly $726 million, compared to $276 million for women. Costs of death were the highest proportion of total costs for both men and women, accounting for more than 70% of the total smoking-attributable costs. Health professionals, legislators, and employers should note that the cost of illness related to smoking is paid for by non-smokers as well as smokers in the form of taxes to support medical care and other programs required by those whose illnesses are related to smoking. With the overall cost attributed to smoking in 1989 at more than $1 billion, this translates to $694 per person age 35 and older, and approximately $304 per person for the entire state of Oklahoma.

Call for Resolutions

All resolutions to be presented to the Oklahoma State Medical Association House of Delegates Annual Meeting must be received in the executive offices no later than thirty (30) days prior to the meeting. This year's meeting will be April 23-25, 1993, at the Adam's Mark Hotel in Tulsa.

County medical societies or individuals wishing to submit resolutions should mail them to OSMA, 601 Northwest Expressway, Oklahoma City, OK 73118. Should you need assistance in drafting such resolutions, please contact the executive offices.

Resolutions must be submitted on or before March 23, 1993

In Memoriam

1992	
John Moore Campbell III, MD	January 24
Bruce Ratliff Hinson, MD	January 24
Louis Carroll Taylor, MD	February 3
Earl Russell Muntz, MD	February 4
Claude Marion Bloss, Jr., MD	February 24
Oliver James Hagg, MD	March 31
Francis Patrick Cawley, MD	April 17
Don Horatio O'Donoghue, MD	April 20
Billie Gene Henley, MD	April 24
Arlo Kenneth Cox, MD	April 27
Charles Victor Williams II, MD	May 1
Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George C. dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28
1993	
Howard Smotherman, MD	January 11

OSMA Physician Recovery Program

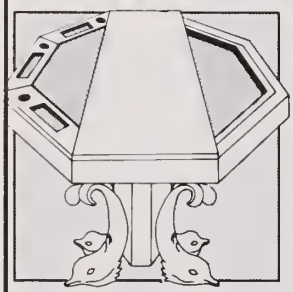
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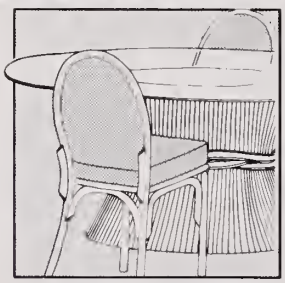


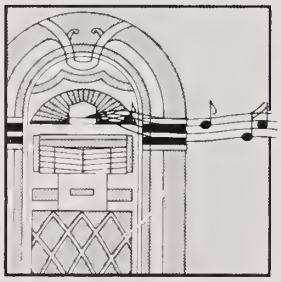
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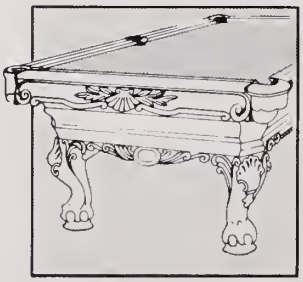

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AMA surveys women physicians: 74% report sexual harassment

A high percentage of women physicians have experienced sexual harassment at some time, according to a report published in the AMA's "Member Matters." Among 1,400 respondents, nearly 74% said they had experienced sexual harassment—80% in medical school, 65% in residency, and 42% while in practice. Some 68% of the respondents (who were asked to check all applicable categories) said they were harassed by colleagues; 66% by management staff; and 31% by patients. In 80% of the cases, no corrective action was taken; physicians who did not report the incidents cited fear of the impact on their careers.

75 Years Ago

■ OKC physicians report variety of cases for St. Anthony clinical society

Dr. Edward F. Davis presented the following cases:

J.M., male, aged 34, farmer. While burning brush, got some foreign substance (probably ashes) in left eye which soon became congested and painful. In a few days a "scum" came on the cornea and vision was impaired. Had no special treatment for five weeks when examination showed a this scar over lower part of cornea and an indolent ulcer above with considerably vascularization surrounding ulcer. There was little pain and only slight discharge. The ulcer resisted all ordinary treatment and was becoming larger gradually. The base was clean and slightly bulging and only the edge took fluorescin stain. One morning, he reported that he had had a sudden pain in the eye and a quantity of watery liquid escaped the preceding night. Inspection revealed an irregular line in the floor of the ulcer, indicating it had ruptured. Following this, all symptoms abated, conjunctival congestion passed away and the corneal vessels disappeared in a few days. This case is shown on account of the fact that there was a spontaneous Seamisch operation. This incision was to have been made on this particular day but nature made it unnecessary.

Mrs. J., aged 72. Cataract extraction in right eye six months ago. Previous laboratory findings of blood, urine, and conjunctival secretion was negative. Vision, at that time, merely perception of light. Recovery was rapid but vision was only about 10-200 and was not

improved by glasses. The poor vision is due to a pre-existing choroiditis. the left eye was operated on ten weeks ago but recovery was complicated by a slow, painless plastic iridocyclitis with occlusion of the pupil and great thickening of the iris. An attempt was made to incise the pupillary membrane and to remove a part of the thickened iris but the new formation was so dense that this could not be done satisfactorily and no further efforts were made. In this case the patient is in no worse condition as a result of the operations on the second eye and the net result in the first eye is that she is able to get around which she could not do in safety before.

Report of case of Mrs. R., aged 51. Has been on Allen treatment for diabetes mellitus. She became sugar-free and at the same time developed a disturbance of vision so sever as to be unable to see and ordinary type written page. Examination showed a marked oedema of the optic nerve which gradually cleared up after she had been sugar-free some days and her sugar tolerance had been increased. This is a frequent finding in the cases reported by Joslin.

Dr. Smith reported cases of two men burned with steam following the bursting of a boiler. The men arrived at the hospital several hours after the accident occurred. Both had had their bodies and limbs bandaged and a hypodermic of morphine but on arrival complained very much of pain and were in a state of considerable shock. Very little time was spent in the removal of their clothing and superficial cleansing until they were put to bed, which was covered with a cradle and fitted with an electric light in such a way that none of the bed linen except that on which they lay came in contact with their bodies.they soon became warm and ceased to complain of such severe pain.

Both patients were badly burned. F.E.S., age 41, had burns of the first or second degree covering at least three fourths of the body surface. These burns were chiefly on the face, back, buttocks and limbs. The other patient, M.D.J., age 43, was burned over similar areas but the surface covered not being over two-thirds of the body surface.

Both patients were treated as follows: after they became warm they were bathed with a tepid dilute solution of sodium bicarbonate every two hours. SMall quantities of a bicarbonate solution was given by mouth and large amounts of the solution was administered per rectum by the Murphy drip. F.E.S. on the third day developed a sever nephritic lesion as was shown by the urine analysis, however no acetone appeared. The heart muscle became weak, the pulse became rapid and the patient died on the fourth day following twenty-four hours of delirium.

The second patient, E.S.J., was nearly as badly burned as the first but his kidneys seemed to stand the sever toxemia better than those of the first. the urine analysis of this patient showed a slight nephritis. No acidosis developed but a slight glucosuria which cleared up in a few days. After four weeks stay at the

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Case Reports *(continued)*

hospital, with urine negative, a temperature practically normal, the patient feeling fine and in good condition except for some small areas over his legs and buttocks which required skin grafted, he was removed to the railroad hospital in St. Louis for further treatment.

We were greatly pleased with the open air method of treatment. We especially noted that the wounds became only very slightly infected, and the en complained very little of pain. the wounds of the man who recovered were deep and extensive and we feel quite sure that the constant use of sodium bicarbonate solution, both internally and externally, prevented a severe acidosis which superimposed on the kidney lesion which he developed would have caused the death of our patients.The open air method gives free drainage, preventing the necrotic material from being absorbed and is of vital importance just as it is in draining a pus cavity to prevent absorption of pus.

Drs. J.W. Riley, S.R. Cunningham and H. Reed in discussing the report cited similar cases in which most satisfactory results were obtained by the open air method.

—From "Proceedings of St. Anthony's Hospital Clinical Society"
J Okla State Med Assoc
Vol. 11, No. 1, Jan. 1918

■ Editorial: 'The Oklahoma Doctor's Duty to the Annual Meeting'

Year after year we have heard excuses, reasonable and unreasonable, given as a reason for not attending the annual meeting. Usually they are from men who did not attend the year before, often on account of some fantastic idea that positively all the wheels in the neighborhood would stop revolving if they should leave the engine of the universe unattended or in the hands of some rival engineer during their absence from home.

Now ordinarily these excuses go, but this time they should not be forgotten. If there was ever a time when the recluse should be rudely jarred from his self-complacent, stay-at-home, sufficient-unto-myself attitude, it is now. Men never needed the stimulating ideas of their fellow practitioners as they do now. No future medical generation will have to face the problems, so completely, we may say, of a socialistic nature, if that word means the individual's best effort for the good of all, as our profession is now facing and must solve and make the best of.

Contact with you fellow physician will reveal a world of shorts cuts and suggestions for improvement in the handling of your every day problems. If you know how to do something better than he does, and of course you admit you do, it is now your duty to help along the general good by telling him how to do it properly.

Drop your absorbing problems and make arrangements to attend the Tulsa meeting. Everything calls you to this sacrifice.

—Editorial, Unsigned
J Okla State Med Assoc
Vol. 11, No. 5, May 1918

[The 1993 OSMA Annual Meeting, also in Tulsa, will be April 23-25 at the Adams Mark Hotel.]

Deaths

Roy Willie Anderson, MD
1907 - 1992

OSMA Life Member Roy W. Anderson, MD, of Cordell, died December 8, 1992. A 1939 graduate of the University of Oklahoma, Dr. Anderson completed his internship in Vancouver, British Columbia, in 1940, and then returned to Oklahoma. He worked for the State Department of Health in Guthrie, Clinton, and Weatherford before establishing his general practice in Cordell. During the war in Viet Nam, Dr. Anderson served as a volunteer surgeon with the AMA Volunteer Physicians for Viet Nam.

Eugene Arthur Durso, MD
1925 - 1992

Eugene A. Durso, MD, retired and living in Sun City, Ariz., died December 28, 1992, in Tulsa. Born in Pittsburgh, Pa., Dr. Durson completed his medical doctor's degree at the University of Pittsburgh in 1949, specializing in obstetrics and gynecology. In 1967 he completed a residency in radiology and narrowed his practice to mammography. The following year he moved to Norman. Dr. Durso was an associate professor in the Department of Radiology, University of Oklahoma Medical Center (now OUHSC). He served as a chief medical officer with the U.S. Navy during both World War II and the Korean conflict. *(continued)*

OSMA TOLL-FREE NUMBER
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Howard Smotherman, MD
1933 - 1993

Bethany obstetrician-gynecologist Howard Smotherman, MD, died January 11, 1993. Dr. Smotherman was graduated from the University of Oklahoma School of Medicine in 1958. He completed his internship at St. Anthony Hospital and his residency at University Hospital, both in Oklahoma City. From 1962 to 1964, Dr. Smotherman served as a captain in the U.S. Air Force and from 1964 to 1969 as a clincal instructor at his alma mater. He received his ob-gyn board certification in 1967.

CLASSIFIEDS

Classified ads are 50 cents a word, with a minimum of $25 per ad. A word is one or more characters bounded by spaces. Box numbers will be assigned upon request and will add 6 words to the total. Ads will not be accepted on the telephone or by facsimile. Payment or PO number must accompany all ads. Mail ad with payment to OSMA Journal, 601 Northwest Expressway, Oklahoma City, OK 73118. Deadline is the first of the month preceding the month of publication.

Physicians Wanted

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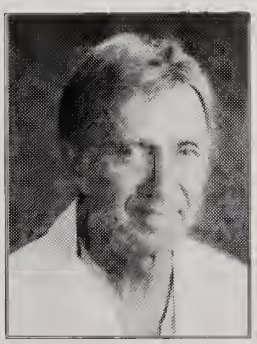
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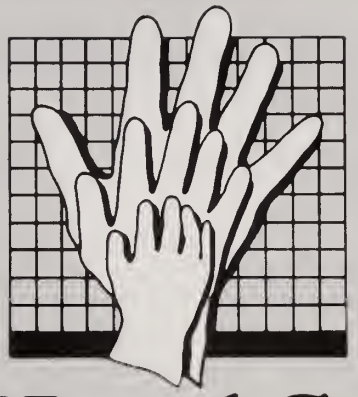
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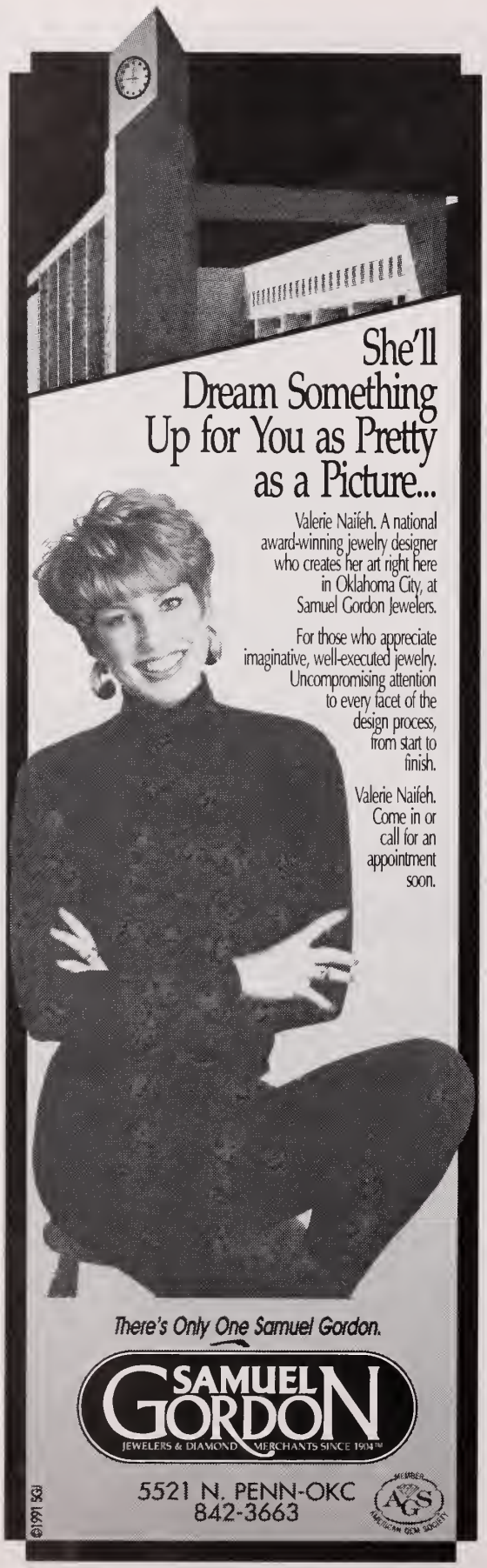
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Articles submitted for publication become the sole property of the Journal and must not have been published elsewhere. The Editorial Board reserves the right to edit any material submitted. Manuscripts must be typewritten in a standard size and typeface suitable for scanning, double-spaced, and submitted in duplicate (original and one copy). Authors who can do so are encouraged to submit their manuscripts on computer disk as well; disk should be in ASCII/text-only format or DOS WordPerfect and clearly labeled with the manuscripts' title and author. The Journal does not assume responsibility for the statements or opinions of any contributor.

Style

All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style*. An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

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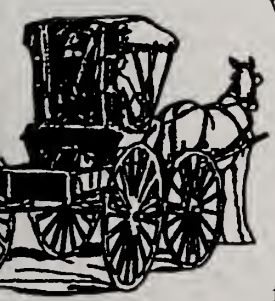
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$55 Million and Counting

In a day when the bottom line is often measured in dollars, the AMA-ERF has achieved remarkable success. Since it was founded 40 years ago, the foundation has distributed $57 million to help U.S. medical students and schools achieve excellence in education. In 1991 alone, the foundation distributed $1.9 million to medical schools and students, as well as granting funds to assist biomedical research projects.

Your gift, regardless of the amount, combined with other donations, means that the medical schools receive a sizeable amount of money for their programs. You also have the option of designating which school will receive your contribution—your alma mater, local medical school, or one whose work you respect. There is the option of whether your contribution is for the Medical School Excellence Fund, which allows schools to use the fund where they are needed most, or the Medical Student Assistance Fund, which enables medical schools to provide financial aid to students through scholarships and loans.



You know how your money is used by the medical school—for visiting faculty, library improvements, laboratory equipment, etc.—since auxiliary leaders are in contact with the deans and can share this information with you. You let the public know that the medical community is committed to quality health and medical care—this helps to strengthen relationships between physicians and their patients. Your participation in medical community fund-raisers such as raffles, auctions, and sports events increases awareness of the AMA-ERF.

AMA-ERF President William E. Jacob, MD, assistant vice-president for health science at the University of Minnesota, says, "These funds in a very direct and real way make my life, the lives of my academic colleagues, and most important, those of the medical students, much easier."

Dr. Jacob credited the AMA Auxiliary with providing the funds to help AMA-ERF accomplish its goals. "Without the valuable time that auxiliary members spent on the truly innovative and imaginative approaches to fund-raising, AMA-ERF wouldn't be able to constantly reach and exceed goals," Dr. Jacob said.

With spiraling costs and shrinking sources of funds, our schools depend on private sources to help meet the educational needs of the country's future physicians. As one supporter put it, "Whether my child chooses to be the physician and/or inevitably becomes the patient, I will have participated in the quality of care given."

In 1992-93, AMA Auxiliary AMA-ERF Committee has set a goal to increase total contributions to the foundations by 2%. Each of us will play a key role in the success of this effort by giving more to our Holiday Sharing Card, using the all-purpose card as an appropriate gift for numerous occasions—birthdays, thank-you's, holidays, graduation, job promotion, appreciation to dentists, accountants, clergy, legislators, honor an out-going president, thank-you to a committee member, or express sympathy by offering a memorial donation.

There are also informal cards—the inside is blank so you can write a note or letter. The mini-fundraisers this year are new ideas and everyone can be a part of any one or both. For the "Field of Dreams" we are asked to give the equivalent of one night out on the town as a contribution to any of the choices listed above. Your "Field of Dreams" donation can be sent to our state AMA-ERF chair—"K" Caldwell, 3930 S. Lewis, Tulsa, OK 74105.

Back to the Past: Antique Sale and Victorian Tea

At convention time, April 23-25, 1993, at the Adams Mark Hotel in Tulsa, we will have a Victorian Tea and Antique Auction. This will give auxilians an opportunity to wear hats, gloves, purses, or really dress in Victorian period clothes and attend a tea in one of the Tulsa homes. We will auction antique items we have been collecting this year with anticipation of a good time and going over our increased goal of 2% for AMA-ERF. Plan to come to convention and help us meet our goal.

—Dawn Wood
Co-Chair, AMA-ERF

THE LAST WORD

■ **Oklahoma physicians are reminded that** continuation of their liability insurance from the Physicians Liability Insurance Company (PLICO) is contingent on their attendance at an approved loss prevention seminar every three years. Any physician who last attended such a seminar in 1990 *must* attend another in 1993. Seminar schedules and registration information appear regularly in *PLICO News.* Watch for them.

■ **Packets of information about Oklahoma's new** living will law have been produced as a joint effort of the Oklahoma State Medical Association and the Oklahoma Bar Association. Included in the packet are a copy of the new living will, a brochure explaining the law and how to complete the form, and a wallet card indicating that a living will has been executed by the bearer. The packets are available at no charge to OSMA physicians for distribution to their patients. Order forms were included in the December *OSMA News* and the January issue of *PLICO News.* An order form also appears on page 87 of this JOURNAL.

■ **Personalized license plate seen on a small red** car in north Oklahoma City: 2BEADOC.

■ **The Oklahoma Workers' Compensation Court** is seeking physicians willing to do examinations of and reports about worker's compensation claimants. Those interested should call the court's administrator's office about what type of cases they are willing to review. For additional information, contact OSMA General Counsel Ed Kelsay, (405) 843-9571 in Oklahoma City.

■ **Advice on dealing with the requirements of** the Americans with Disabilities Act is contained in the AMA Video Journal "Physician Guide to ADA." The 14-minute video examines how the ADA applies to physicians as providers of care and as employers. Included with the video is a guidebook, "Americans with Disabilities Act: A Prescription for Compliance," and a list of information resources. The video may be ordered through the AMA's toll-free number, (800) 621-8355; request order No. OP111592CW. The price is $20 for AMA members, $30 for non-members.

■ **The Tulsa County Medical Society (TCMS) re**cently announced its new slate of officers and delegates. President Douglas C. Hubner, MD, will serve with President-Elect Boyd O. Whitlock, MD; Vice-President David J. Confer, MD; and Secretary-Treasurer W. Frank Phelps, MD. Drs. Edythe P. Harvey and Kenneth A. Muckala join Drs. David L. Harper, James A. Johnson, Bill H. Lipe, John A. Minielly, John W. Phillips, and Richard C. Slagle on the Board of Directors. Dr. C. Wallace Hooser has been elected to a three-year term on the Board of Censors, and winning three-year posts as delegates to the OSMA were Vicki C. Baker, MD; Donna J. Brown, MD; Glyn G. Caldwell, MD; John B. Forrest, MD; Robert M. Gold, MD; C. Wallace Hooser, MD; Edward W. Jenkins, MD; Robert M. Melichar, MD; George W. Prothro, MD; David B. Thomas, MD; and Casey Truett, MD.

■ **The AMA has revised its guidelines for ade**quate disability insurance coverage for HIV-infected physicians. Among the necessary ingredients, according to the new guidelines, are: a reasonable definition of "sickness" or "disability"; an "own-occupation" clause qualifying policyholders for disability benefits if they can't continue working in their chosen specialties; guaranteed renewability, assuring that the policy can't be discontinued if the insured develops AIDS; a provision allowing the policyholder to buy additional coverage without a physical examination; and partial disability provisions that allow the insured to collect payment while still working. A report adopted at the AMA's Interim Meeting in December also recommends that all medical schools and residency programs provide insurance with these components.

■ ***Perennial Change,* a history of the Oklahoma** City Clinic by retired clinic physician Edward R. Munnell, MD, was released recently. The book explores the years of growth from the Oklahoma City Clinic's beginning in 1919 and recounts the contributions of the clinic's physicians to medical care in Oklahoma. Copies of the book are available for $19.95 at the clinic's pharmacy, 701 Northeast 10th Street, Oklahoma City, OK 73104.

■ **AMA's headquarters building was the site of** a December 23 rally urging an end to violence against women, sponsored by a coalition of Chicago-area women's groups. AMA officials noted the association is spotlighting the prevention of domestic abuse, emphasizing that doctors have the responsibility not to return people into the circumstances in which they were injured.

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NTRAINDICATIONS

ersensitivity to any component of this medication.

ctive liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs ring pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. olesterol and other products of cholesterol biosynthesis are essential components for fetal development luding synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol thesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may se fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contrain- ated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of child- ering age only when such patients are highly unlikely to conceive and have been informed of the tential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discon- ued and the patient apprised of the potential hazard to the fetus.

RNINGS

er Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated h biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than mes the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been orted in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These normalities were not associated with cholestasis and did not appear to be related to treatment duration. In se patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued n therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are ually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain y also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. rum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., about six-month intervals). Special attention should be given to patients who develop increased transaminase els. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more quent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, n therapy should be discontinued. Persistence of significant aminotransferase elevations following discon- uation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see NTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history iver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). ch patients should be closely monitored, started at the lower end of the recommended dosing range, and ated to the desired therapeutic effect.

eletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been re- rted with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in vastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weak- ss in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy ould be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked vation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weak- ss, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if mark- ly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should o be temporarily withheld in any patient experiencing an acute or serious condition predisposing the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major rgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gem- ozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin ether with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients o were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with vastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to sculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving cebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: ug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated imen of pravastatin; the myopathy resolved when clotibrate therapy was stopped and pravastatin treatment ntinued. **The use of fibrates alone may occasionally be associated with myopathy. The combined e of pravastatin and fibrates should generally be avoided.**

ECAUTIONS

neral: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). s should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homo- ous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase ibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying grees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacoki- ics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC ues and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small mple size, the dosage administered, and the degree of individual variability, patients with renal impairment who receiving pravastatin should be closely monitored.

ormation for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness weakness, particularly if accompanied by malaise or fever.

ug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARN- GS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of prav- atin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that y significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cyto- rome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after olestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in availability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, availability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not er the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after lays of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been orted with another drug in this class. Patients receiving warfarin-type anticoagulants should have their pro- mbin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The AUC_{0-12hr} for pravastatin when given with cimetidine was not significantly different from the C for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin en given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 ys, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin d gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In dition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. mbination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was ministered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was ded to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta- ckers, or nitroglycerin.

docrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating olesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible ects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to man chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of vastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chronic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of MG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of ients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. ients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated opriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower olesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, netidine) that may diminish the levels or activity of steroid hormones.

IS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear l infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a se that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 g/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Hardenan gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

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Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

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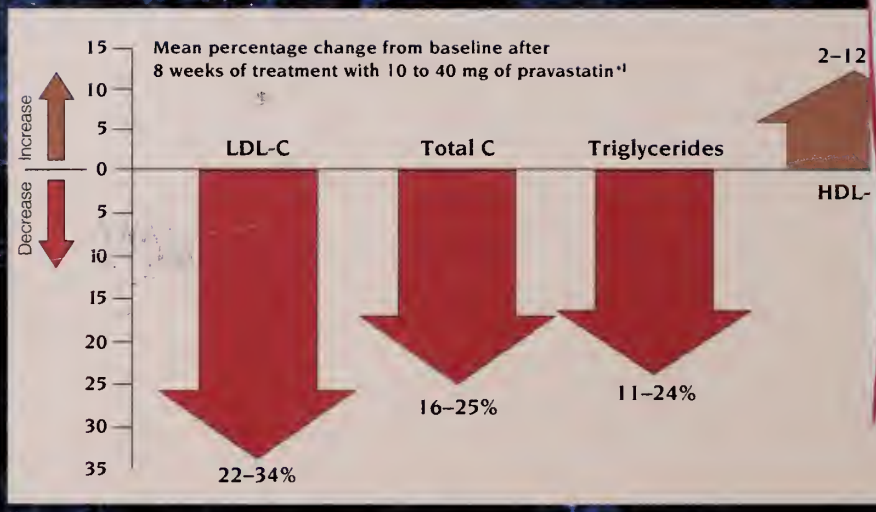
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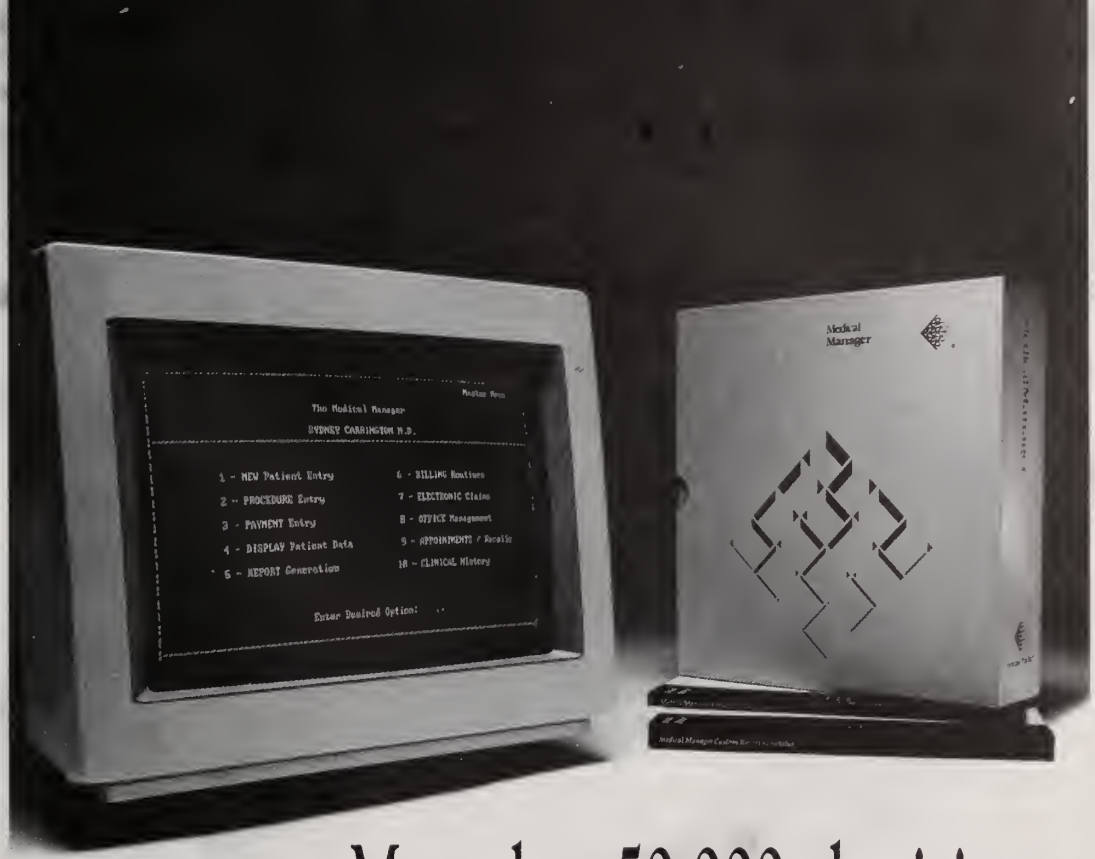
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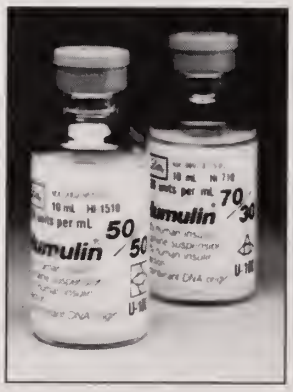
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Ray V. McIntyre, MD

An Outrageous Fortune

In the card game of life, every human being must play out the hand that has been dealt; Mother Nature never reveals the cards. Even though the environment experienced during childhood affects a person's entire life, the most important determinant of that life's possibilities is the reduction division chromosome shake-out of the fertilized ovum. Later events in a human's life story are comparatively minor.

Every person able to read these words can be assumed to have had a survivable chromosome pattern and a tolerable childhood. But any biological reproductive system is subject to fatal chromosome anomalies, and the most tragic anomalies are those that are not immediately fatal. One of the more calamitous is the fate of the anencephalic baby, who is born "in the image," but without a cerebrum.

Related article, p. 128

The anatomical location of the human soul remains debatable after eons of argument, but the idea that our human characteristics depend on a functional cerebrum is questionable only to those mortals who have never dealt with an anencephalic baby or a supratentorial gunshot wound. Most physicians well know that wherein humans are distinguishable from animals, it is the cerebrum that makes it so.

Thus the anencephalic baby lives a short time in biological and legal limbo. Unable to be human without a cerebrum, not yet dead to be buried and forgotten, the anencephalic existence bewilders us with our ethical and moral desiderata. We debate the desirability of using this protoplasm for various transplantation and research projects. We wish anencephalic babies to be fixable, but we cannot even prevent them. If they are not fixable, should we or may we use them to fix someone else who has a cerebrum?

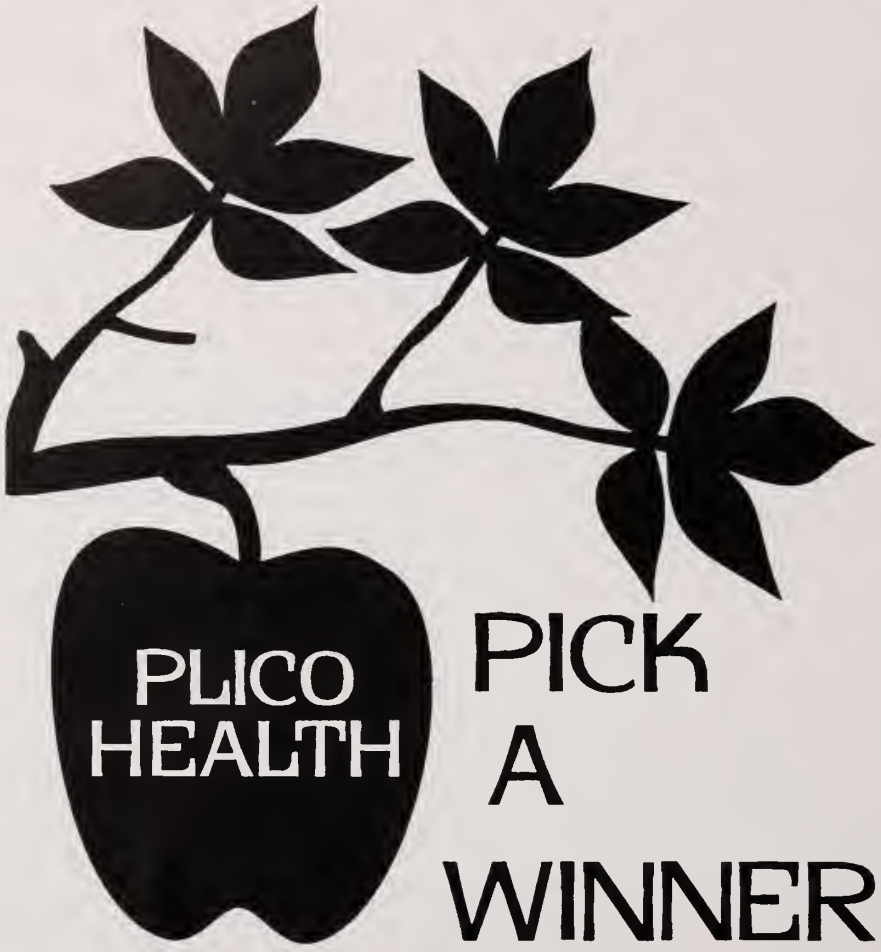
That all transplantation therapy is desperation in action is often forgotten in the physiological chess game of being able to do it, and we tend to forget that many transplantation successes can follow only from another's death. That anencephalic babes are a deficient and sometimes defective source of organs perhaps should not preclude their use. But we should hold for ourselves the higher goal of developing strategies that will end the need for transplantation operations. When medical utopia has been achieved, there will be no need for transplants.

The stark dilemma of the not dead, not human, anencephalic baby also casts a harsh light on another legal deficiency our Oklahoma society could address and solve. The legal definition of brain death in Oklahoma is antiquated by the present knowledge of the functions of the cerebrum and brain stem. The capacity to be human requires a relatively intact cerebrum; therefore it is incorrect for our Oklahoma statute to require the "cessation of... all functions of the entire brain including the brain stem," before a medical determination of death may be rendered. An improved definition of brain death would separate the effects of cerebral destruction and brain stem death, and Oklahoma needs the refinement.

Perhaps it is time for another dialogue between the Oklahoma Bar Association and the OSMA with the objective of refining the statutory definition of death to permit a legal death determination to be made in cases of irreversible cerebral damage—or absence—but in the presence of a still-functioning brain stem.

An improved definition could ease the plight of the families of cerebrum dead terminal patients and the anencephalic babies.

Ray V. McIntyre, M.D.



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PRESIDENT'S PAGE

James D. Funnell, MD

Year Off to a Fast Start



Greetings, and welcome to the real world. Your Oklahoma State Medical Association has been busy, especially since the legislature is in session, and each day is filled with new challenges, surprises, and hard work. Your Council on State Legislation and Regulation continues to work long and hard to review numerous bills and attempt to come up with sound recommendations about them.

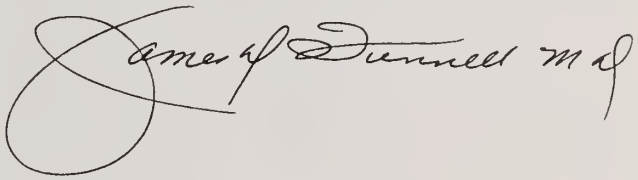
The OSMA also is working vigorously with the Oklahoma Bar Association in support of HB 1296, a bill that will help physicians, attorneys, and all individuals throughout the state who volunteer their time and services. Also, the OSMA has worked hard with the Physicians Assistants in looking at the Physician Assistants Bill, particularly in view of the problems associated with rural health. Your state medical association also has worked very hard in conjunction with the state's ophthalmologists in defining surgery and working with all those concerned with the bill submitted by Senator Stipes concerning laser surgery.

Another interesting committee that has been very busy over the last few weeks is the Workers Compensation Reform Committee, which has met with the judges from the Workers Compensation Court in an attempt to develop helpful reforms for both the legal and the medical interpretations.

Last month was a busy one for leadership training. the national AMA Leadership Conference was held in Atlanta, Ga., and it was followed by your own OSMA leadership program.

An outstanding evening was held by the University of Oklahoma Alumni Association with its Evening of Excellence at the Oklahoma City Marriott Hotel. This year's honorees were Mark Allen Everett, MD, the Deans' Award for Distinguished Medical Service, and Mr. Paul H. Travis, the Dean's Award for Distinguished Community Service.

As we move full speed ahead toward the end of the 1993 legislative session, keep your seat belts fastened and your fingers on the eject button because every day is a new challenge. Fortunately, we have good legislative direction. I would remind each of your to talk with your legislators concerning the bills that affect you and the practice of medicine.



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SCIENTIFIC

Retinoblastoma in the State of Oklahoma: A Clinicopathologic Review

Mark H. Scott, MD; James M. Richard, MD

This is a retrospective review of 56 patients diagnosed with retinoblastoma (Rb) from 1970 to 1990 at either the Dean A. McGee Eye Institute or Children's Hospital of Oklahoma. Twenty-six (46%) patients had somatic Rb and thirty (54%) had germinal Rb. On average, somatic disease presented at 20.5 months and germinal disease at 11.7 months. Nine (16%) of our patients have died; of these, metastatic disease was the cause of death in six patients, whereas a midline pineal tumor (trilateral retinoblastoma) was the cause of death in three patients. Metastatic disease presented an average of 17.5 months after the diagnosis of Rb, and death occurred an average of 10.3 months after the diagnosis of metastasis. Trilateral Rb presented an average of 18 months after the diagnosis of retinoblastoma, and on average death occurred 2 months later. Histopathology was available on forty-nine of our patients. Poorly differentiated tumor histology, optic nerve invasion of tumor cells past the surgical plane of transection, and choroidal invasion of tumor cells appear to be significant histological markers for developing metastatic disease. The cytogenetics, current therapy, and related management of retinoblastoma are reviewed.

During this century, retinoblastoma has evolved from an almost uniformly fatal disease to one in which the affected individual can be saved in approximately 90% of cases.[1] Retinoblastoma remains the most common intraocular tumor of childhood, with an incidence of 1:15,000 to 1:30,000 live births.[2] Many clinicopathologic studies have been done to determine which gross and microscopic features have prognostic value. However, many conflicting reports have arisen in the literature. For example, Carbajal,[3] Brown,[4] Zimmerman,[5] and Parkhill and Benedict[6] all found that choroidal invasion by retinoblastoma was associated with a poor prognosis, whereas Redler and Ellsworth,[7] and Kobrin and Blodi[8] found either no association or an association only when the choroid had massive invasion.

Other conflicting reports have occurred regarding the degree of tumor differentiation and survival. Taktikos,[9] and Kobrin and Blodi[8] did not find a significant association, whereas Tso et al,[10] and Parkhill and Benedict[6] found that poorly differentiated tumors were more lethal. A similar lack of agreement has arisen regarding tumor laterality. Stannard et al[11] found that patients with unilateral retinoblastoma have a worse prognosis than those with bilateral disease. Carbajal,[3] and Kobrin and Blodi[8] found a better prognosis with unilateral disease. There is, however, more uniform agreement that optic nerve invasion posterior to the lamina cribrosa worsens the prognosis.

We review cases of retinoblastoma that were seen at either the Dean A. McGee Eye Institute or Children's Hospital of Oklahoma from 1970 to 1990. We examined the clinical presentation of our patients as well as the histopathology their tumors to determine which patients were at risk for developing metastatic

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disease or trilateral retinoblastoma, the main causes of death in retinoblastoma.

Retinoblastoma Cytogenetics

During embryogenesis, the developing retina is comprised of multipotential embryonic cells which are capable of differentiating into photoreceptor cells. It is from these cells that retinoblastoma arises. Advancements in the field of molecular genetics have led to the discovery and successful cloning of the retinoblastoma gene.[12,13] This gene, located in the 1-4 band on the long arm of chromosome 13 (13q14),[14,15] belongs to a class of genes called "tumor suppressor genes,"[16,17] and acts as a recessive oncogene at the cellular level. The normal gene produces a "suppressor substance" that controls cellular growth. However, when both normal genes in a single retinoblast are inactivated, either by a mutation or deletion, then uninhibited cellular growth of that specific retinoblast leads to tumor formation.

Retinoblastoma (Rb) is known to occur in hereditary, non-hereditary, and chromosomal deletion forms. As used in this article, *hereditary* Rb refers to clinical situations in which there is a positive family history of the tumor, or in the case of sporadic disease, in which the individual has bilateral or multifocal unilateral disease. No chromosomal defect is found in peripheral lymphocytes. In the *chromosomal-deletion* form of the tumor, the peripheral lymphocytes have a deletion of chromosomal region 13q14. The term *non-hereditary* Rb is applied to individuals with unilateral disease, no family history of the tumor, and no chromosomal abnormality in peripheral lymphocytes. Since both the hereditary and chromosomal-deletion forms of Rb can be passed on from generation to generation, they will collectively be referred to as *germinal* Rb. Non-hereditary Rb will be referred to as *somatic* Rb since both mutational events occur in somatic retinoblasts.

In hereditary Rb the first mutation is either inherited or arises spontaneously during gametogenesis. Therefore, every cell in the body contains one functional and one inactivated gene. The functional gene will prevent malignant transformation. If, during retinal development, a second mutation were to occur at the 13q14 locus of a developing retinoblast, then homozygosity for the suppressor gene would be produced and tumor formation would occur. In 1971 Knudson developed the hypothesis that retinoblastoma is a tumor caused by two mutational events.[18] He postulated that the mutation rate was 10^{-7} per year. It has been calculated that the development of each retina requires 10^8 cellular divisions. Strictly by chance, then, during retinal development, an individual who is heterozygous at the Rb locus is likely to develop at least one cell in each retina that will have both genes inactivated. Since only one mutational event is required for tumor formation to occur, it follows that hereditary (germinal) Rb is often bilateral, multifocal, and tends to occur earlier than somatic Rb, which requires two mutational events.

In non-hereditary (somatic) Rb, the patient inherits two normal genes, and sequential inactivation of each gene results in tumor formation. Because the probability of this occurring in more than one developing retinoblast is small, these cases are unilateral, unifocal, and tend to occur later. These patients have no increased risk for secondary nonocular tumors. Table 1 compares germinal and somatic retinoblastoma.

Deletion of the 1-4 band on the long arm of chromosome 13 (Fig. 1) was first demonstrated by Francke in the mid 1970s.[21] The chromosomal-deletion form of Rb is found in only 5% of patients with germinal Rb. Current cytogenetic techniques require loss of at least 2%

Table 1. Features of Germinal and Somatic Types of Retinoblastoma

	Germinal	Somatic
Age at Dx	Earlier	Later
Laterality	Unilateral or bilateral	Unilateral
Transmission to offspring	Offspring affected	Offspring unaffected
Secondary non-ocular tumors	Occur with greater frequency	Do not occur with greater frequency

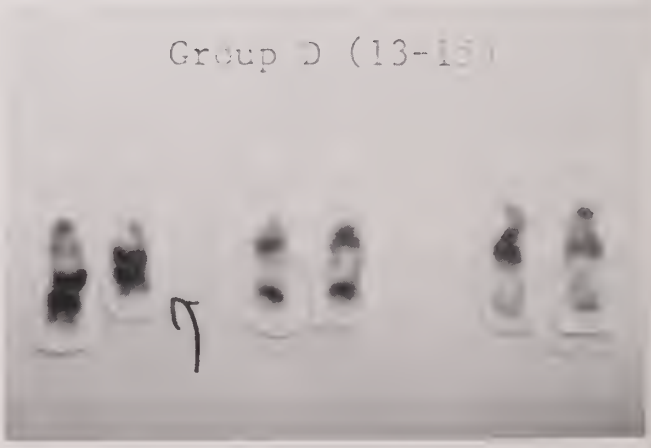


Figure 1. Karyotype demonstrating deletion of a portion of the long arm of chromosome 13 ("13q-").

to 3% of the chromosome before a visible deletion can bedetected.[22] However, since the Rb gene is comprised of only a fraction of DNA material, many more microscopic deletions are probably present that are just not detectable by current techniques. Table 2 summarizes the different genotypes at the Rb locus.

Table 2. Retinoblastoma Genotypes at the Rb Locus

Genotype	Non-Hereditary (Somatic)	Hereditary (Germinal)	13 Deletion (Germinal)
Constitutional	Rb+/Rb+	Rb+/rb–*	Rb+/–
Tumor	rb–/rb– or rb–/–	rb–/rb– or –/rb–	rb–/– or –/–

*The genotype referred to when a patient is said to carry the retinoblastoma "gene."

Materials and Methods

We performed a retrospective chart review on 56 cases of retinoblastoma that presented to the Dean A. McGee Eye Institute and Children's Hospital of Oklahoma from 1970 to 1990. All tumors were staged using the Reese-Ellsworth classification system found in Table 3. The Reese-Ellsworth classification takes into account the number, size, and location of tumors within the eye and presence or absence of vitreous seeding. We analyzed sex, initial presentation, laterality, family history of retinoblastoma, age at diagnosis, cause of death, and tumor histopathology.

Forty-nine of the 56 patients had histopathological specimens available. We looked at both tumor differentiation and invasion characteristics in evaluating each specimen. Tumor differentiation was categorized as well differentiated, moderately well differentiated, or poorly differentiated. Tumor invasion was classified as no invasion, choroidal invasion, optic nerve invasion not past the surgical plane of transection, or optic nerve invasion past the surgical plane of transection.

Table 3. Reese-Ellsworth Staging of Retinoblastoma

Group	Description
Ia	Solitary tumor, less than 4 DD in size, at or behind equator.
Ib	Multiple tumors, none over 4 DD in size, all at or behind equator.
IIa	Solitary tumor, 4-10 DD in size, at or behind equator.
IIb	Multiple tumors, 4-10 DD in size behind equator.
IIIa	Any lesion anterior to the equator.
IIIb	Solitary tumors larger than 10 DD behind equator.
IVa	Multiple tumors, some larger than 10 DD.
IVb	Any lesion extending to the ora serrata.
Va	Massive tumors involving over half the retina.
Vb	Vitreous seeding.

DD = disc diameters

Results

Of the 56 patients studied, 40 (71%) were male and 16 (29%) were female. Reasons for evaluation included leukocoria (64%) (Fig. 2), strabismus (21%), positive family history for Rb (11%), and decreased vision (4%). Nine of the 56 patients (16%) had a positive family history for Rb.

Somatic Rb (sporadic, unilateral, unifocal disease) occurred in 26 patients (46%). Bilateral disease occurred in 27 patients, and multifocal unilateral disease occurred in 3 patients. Since multifocal unilateral disease carries the same prognostic significance as bilateral disease, we classified these together as germinal retinoblastoma, and they account for 54% of our patient population. The average age of presentation for somatic retinoblastoma was 20.5 months while germinal retinoblastoma presented at 11.7 months.

Tissue specimens were available for histopathologic review in 49 of our 56 patients. Twenty-two patients



Figure 2. Leukocoria, right eye.

had poorly differentiated tumors (Fig. 3), 16 had moderately well differentiated tumors (Fig. 4), and 11 patients had well differentiated tumors (Fig. 5). Choroidal invasion (Fig. 6) was present in 11 specimens. Optic nerve invasion (Fig. 7) was evident in 9 patients, 4 of which had invasion past the surgical plane of transection (Fig. 8). Twenty-nine patients had no histologic evidence of tumor invasion.

Nine of our patients have died (16%). Six expired as a result of metastatic retinoblastoma, and 3 died from an intracranial pineal tumor (Fig. 9) that, in association with bilateral retinoblastoma, is termed "trilateral retinoblastoma."[23-25]

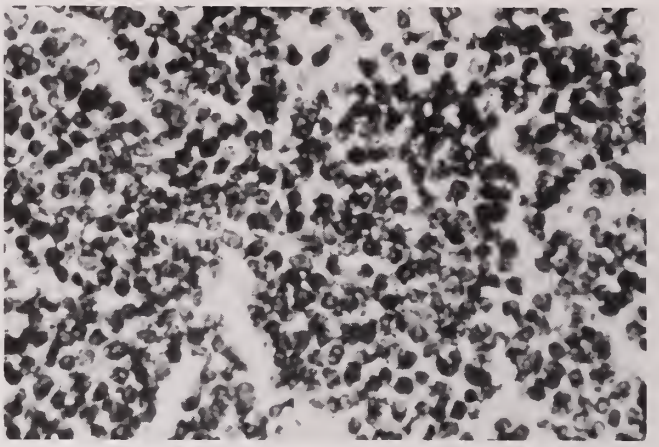


Figure 3. Poorly differentiated retinoblastoma.



Figure 6. Choroidal invasion by retinoblastoma cells.

Discussion

This retrospective study was undertaken to see if we could determine clinical as well as histologic risk factors for the development of metastatic or trilateral retinoblastoma and also to compare our results in Oklahoma to those nationally. The male predominance in our study is not supported in larger studies by Abramson, who found no sex predilection.[26] The reason for this is not clear.

Sixteen percent of our patients had a positive family history for retinoblastoma. This percentage is twice that of Ellsworth's large review, which found a positive family history in 8% of cases.[27] Of interest, however, was that 70% of our patients with germinal Rb had no family history of disease. We can assume that these are either new germinal mutations or deletions that occurred during gametogenesis or inherited mutations from a parent who did not express the defect.

Our finding of leukocoria and strabismus as the two most common presenting signs for Rb is well recognized in the literature. These two objective signs account for approximately 85% of initial presentations to the ophthalmologist. Since these findings can be detected by the pediatrician during routine check-ups, this helps to underscore the importance of direct ophthalmoscopy and ocular alignment examination as a part of every pediatric office visit. It should also be noted that even though these massive tumors will often fill half of the eye, a child will rarely complain of decreased vision.

Somatic Rb was present in 46% of our patients while germinal Rb was present in 54%. These percentages are consistent with a study of 1,147 patients by Abramson, who found unilateral Rb in 40% and bilateral Rb in 60%.[26] The average age of presentation for somatic Rb was 20.5 months. Germinal Rb presented at an average age of 11.7 months (Table 4). These results are similar to those of Abramson, who found that bilaterally afflicted children were diagnosed at an average age of 13 months, compared to the average age of 24 months for unilateral Rb patients.[26] These findings lend support to Knudson's hypothesis that the expression of Rb requires at least two sequential mutational events.[18]

The distribution of somatic vs. germinal mutation according to age (Table 4) reveals that 65% (17/26) of patients presenting under the age of one year had germinal retinoblastoma, whereas 70% (7/10) of the patients presenting after the age of 2 years had somatic retinoblastoma.

A summary of the age vs. the stage at the time of diagnosis is presented in Table 5. The laterality for each subset is displayed. From this table it can be seen that regardless of the age at diagnosis, the most common stage of disease presentation is Stage V. Table 6 organizes the same data in a slightly different way to

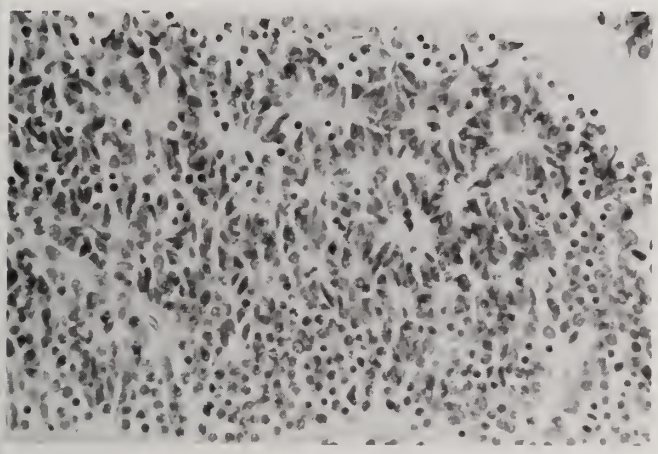


Figure 4. Moderately well differentiated retinoblastoma.

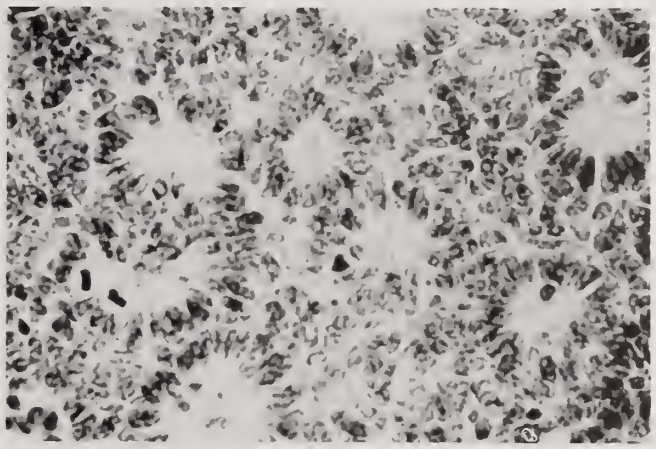


Figure 5. Well differentiated retinoblastoma.

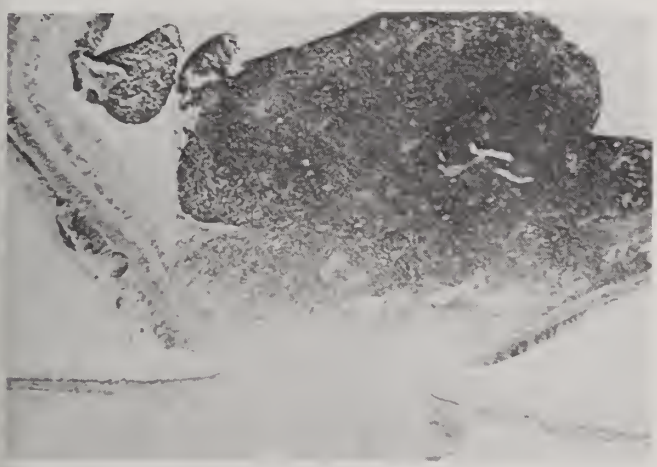


Figure 7. Optic nerve invasion by retinoblastoma.

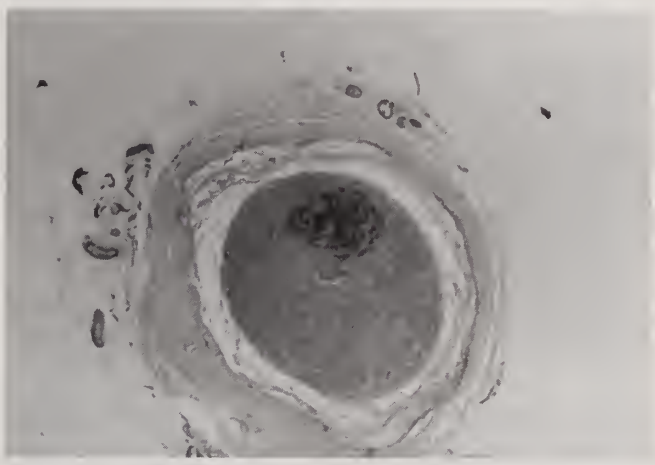


Figure 8. Optic nerve invasion by retinoblastoma beyond the surgical plane of transection.

illustrate the age range at which each Reese-Ellsworth stage most commonly presents. Although the most common stage of tumor at presentation is Stage V, the age at which Stage I disease is usually diagnosed is 0 to 3 months. Stage II disease presents most commonly at 4 to 6 months, Stage III from 13 to 24 months, Stage IV from 0 to 3 months, and Stage V peaks at 13 to 24 months. These findings are similar to a study by Rubenfeld who performed a retrospective review on 358 patients with Rb.[28]

Table 4. Distribution of Cases

Years	Somatic	Germinal
0-1	9	17
1-2	10	10
2-7	7	3

Examination of both somatic and germinal groups reveals that Stage V disease predominates at any age. Table 7 separates somatic from germinal disease, as



Figure 9. Axial computed tomography of brain showing large midline pinealblastoma of "trilateral retinoblastoma."

well as early from advanced tumors. Ninety percent (27/30) of patients with germinal disease had presented by 2 years of age, whereas only 73% (19/26) of patients with somatic disease had presented by that same time.

Death occurred in 9 of our 56 patients (16%). Six of these patients died from metastatic retinoblastoma. The remaining 3 expired from a midline pinealblastoma referred to as "trilateral retinoblastoma." Analyzing the 6 of 56 patients (10.7%) who developed metastatic disease, 3 had bilateral disease and 3 had unilateral disease. Metastatic disease presented an average of 17.5 months after the diagnosis of retinoblastoma. Death occurred an average of 10.3 months after the diagnosis of matastases. Since metastatic disease has an essentially 100% mortality rate, one of the important aspects of this study was to see if any histologic clues that would predispose a patient to metastatic disease could be determined. Of the 11 patients with choroidal invasion of tumor, 4 (36%) developed metastatic disease. Optic nerve invasion past the surgical plane of transection occurred in 4 patients, 2 (50%) of which went on to develop metastases. Lastly, 22 patients had poorly differentiated retinoblastoma, and 5 of these patients (23%) developed metastatic disease. Therefore, 5 of the 6 patients who died of metastatic disease had poorly differentiated tumors. Three patients had choroidal invasion only, 1 had optic nerve invasion past the surgical plane of transection only, 1 had both of the above, and 1 patient had no evidence of invasion.

Trilateral retinoblastoma was the cause of death in 3 patients. Only patients who carry the retinoblastoma gene or who exhibit a 13q14 deletion are at risk for developing trilateral Rb. In our study, 3 of the 30 patients (10%) with germinal disease developed pineal tumors. These patients presented an average of 18 months after the initial diagnosis of germinal retinoblastoma. These unfortunate patients died an average of 2 months after the diagnosis of trilateral Rb. The tumor pathology showed that all three patients had well differentiated tumors with no evidence of optic nerve or choroidal invasion. Of interest is that 2 of the 3 patients (66%) had a positive family history for retinoblastoma. Since only 9 of our 30 patients (30%) with germinal disease have a positive family history for Rb, we believe that patients with a positive family history are at increased risk of developing pineal tumors. This is supported by Holladay's review of 35 patients with trilateral Rb, 68% of which had a positive family history for Rb.[29]

In summary, we believe that laterality is not a risk factor for metastatic disease since of our 6 patients with metastatic disease, 3 had unilateral disease and 3 had bilateral disease. The later presentation to the ophthalmologist does appear to be a significant factor. In our 3 germinal Rb patients that developed metastatic disease, the average age at presentation was 15.3 months, compared to 11.7 months for the remaining patients with germinal disease. Our somatic unilateral patients who developed metastatic disease presented at 37.6 months compared to 20.5 months for somatic unilateral patients who did not develop metastatic disease. Tumor invasion of the optic nerve past the surgical plane of the transection carries the largest risk of metastatic disease (50%). Choroidal invasion of tumor carries a 36% risk, and poorly differentiated tumors carry a 23% risk.

There do not appear to be any clear-cut risk factors for the development of trilateral retinoblastoma. Of interest, however, is the high percentage of these patients who

Table 5. Age vs Stage at Diagnosis

Stage of Tumor	Type	Age at Diagnosis (months) 0-3	4-6	7-12	13-24	25-36	>36
I	U	0	0	0	0	0	0
	UG	1	0	0	0	0	0
	B	1	0	0	0	0	0
II	U	0	2	0	0	0	0
	UG	0	0	0	0	0	0
	B	0	0	0	0	0	0
III	U	0	0	1	3	0	0
	UG	0	0	0	0	1	0
	B	0	0	0	0	1	0
IV	U	0	0	0	0	0	0
	UG	0	0	0	1	0	0
	B	3	1	0	0	0	0
V	U	2	2	2	6	4	3
	UG	0	0	0	0	0	0
	B	1	4	6	9	1	0

U = unilateral somatic Rb = 26 patients
UG = unilateral germinal Rb = 3 patients
B = bilateral germinal RB = 27 patients

Table 6. Age Range in Which Each Reese-Ellsworth Stage Most Commonly Presents

Stage	Age (mos.)
I	0-3
II	4-6
III	13-24
IV	0-3
V	13-24

have a positive family history for retinoblastoma. We believe these patients should be followed more closely for the development of midline intracranial tumors with neuro-imaging of the brain using magnetic resonance imaging (MRI) every 6 months until age 6 years.

Therapy

The treatment of eyes that harbor retinoblastoma has changed considerably over the past decade. The principal considerations in determining therapy include whether involvement is unilateral or bilateral, whether there is vision or any potential for vision, whether the tumor is confined to the globe or if there is extension to the choroid or optic nerve, and whether there is orbital, central nervous system, or hematogenous extension.

Enucleation is still the most frequent treatment for retinoblastoma. It is generally indicated when there is no chance for useful vision, or when there is massive vitreous seeding of tumor, iris neovascularization, or ciliary body and iris involvement by the tumor. In cases of bilateral retinoblastoma, the more severely affected eye is enucleated, and the less affected eye managed by more conservative means, which may include cryotherapy, radiation therapy, and/or photocoagulation. However, if both eyes are massively infiltrated with tumor and no useful vision is possible, then bilateral enucleation is indicated.

Cryotherapy using the triple freeze/thaw method is employed against tumors that are located in the peripheral retina anterior to the equator, are clearly confined to the retina, and are generally no more than 2.5 mm in diameter or 2.0 mm thick.[30] If vitreous seeding of tumor cells is present, the cryotherapy will probably fail to control the tumor.[31]

External beam radiotherapy has been an effective and frequently used mode of therapy due to the radiosensitive nature of retinoblastoma. This treatment modality is used when tumors are larger than 3.0 mm in diameter or 2.0 mm thick, regardless of location, or when mild to moderate vitreous seeding of tumor cells is present.[31] Radiotherapy to the orbit is given when (after enucleation) massive tumor infiltration of the choroid or optic nerve is noted histologically.

Episcleral plaque radiotherapy has been used in the treatment of solitary retinoblastoma and for localized recurrences following external beam therapy. It has limited usefulness as the primary initial therapy when treatment to the entire retina is needed.

Photocoagulation of retinoblastoma with a xenon arc laser is indicated if the tumor is confined to the sensory retina, is no more than 3.0 mm in diameter or 2.0 mm thick, and is located posterior to the equator of the globe.[32]

Multiple chemotherapeutic agents have been used in patients with advanced Group IV and V tumors after enucleation with no survival advantage shown over enucleation alone.[33]

Management

The evaluation and longitudinal follow-up of patients with retinoblastoma is another important aspect in the management of these individuals. Since metastatic retinoblastoma is so rapidly fatal, it is important to know the common signs and symptoms by which metastatic disease is first recognized. In a review of 23 cases of metastatic retinoblastoma by MacKay et al,[34] they found that the initial signs of metastases were neurological impairment and an orbital or body mass. Initial symptoms included anorexia, vomiting, and headache. Of interest is that no patient in their series had metastatic disease detected because of an abnormal laboratory test result. Every patient showed either signs or symptoms, and the researchers therefore concluded that no good screening test for metastatic retinoblastoma was available.

Although we concur with their statement, our recommendations for patients continue to be aggressive. We believe that every child should have a pediatric oncological evaluation potentially consisting of karyotype analysis, blood chemistries, CBC, lumbar puncture, bone scan, bone marrow aspiration, and computed tomography or magnetic resonance imaging of the eye, orbit, and brain. Careful ophthalmologic examinations are then done at least every 3 months for the first year, every 4 months the second and third year, every 6 months to 6 years, and annually thereafter. If histology of an enucleated specimen shows a poorly differentiated tumor or massive invasion of the choroid or optic nerve, then bone marrow aspiration and lumbar puncture should be performed at 4, 8, 12, and 16 months.

Table 7. Age at Diagnosis vs Stage of Disease

	Somatic Patients		Germinal Patients	
Age at Diagnosis (mos.)	Stage I-III	Stage IV-V	Stage I-III	Stage IV-V
0-3	0	2	2	4
4-6	2	2	0	5
7-12	1	2	0	6
13-24	3	7	0	10
25-36	0	4	2	1
>36	0	3	0	0
Total	6	20	4	26

Parents should also be counseled concerning the signs and symptoms of metastatic disease listed above.

It is important to stress the need to individualize the care of patients with retinoblastoma. We suggest a team approach with an ophthalmologist, ocular pathologist, pediatric oncologist, radiation therapist, and geneticist. Each can make important contributions to therapeutic decisions and provide useful information for the family. The impact of the diagnosis of retinoblastoma on parents, child, siblings, and relatives transcends almost all of those commonly encountered in our daily practice of medicine. Family dynamics are inexorably altered, and professional counseling should be availed to the family which may include supportive pastoral care, family therapy, and/or psychotherapy.

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Symposium on Antimicrobial Therapy
VI. The Aminoglycosides

Ronald A. Greenfield, MD

This is the sixth in Dr. Greenfield's series of articles on antimicrobial therapy.

The aminoglycoside antibiotics are chemically aminoglycosidic aminocyclitols, defined structurally by the presence of two or more amino sugars joined via a glycosidic linkage to a central aminocyclitol. The family was born with the discovery by Waksman of streptomycin in 1943. Drugs in this family have been the mainstay of therapy for aerobic Gram-negative bacillary infections for over three decades. This role is now being challenged by newer β-lactam antibiotics, as discussed in the previous segments of this symposium, and by the fluoroquinolones, which will be discussed in the next segment. It is therefore important to evaluate the issue of whether or not the evolution of antimicrobial therapy has left aminoglycosides in the same position as dinosaurs. Obviously, if I believed that to be entirely correct, this segment of the symposium would not exist. As will be argued, for empiric therapy of an infection presumed due to aerobic Gram-negative bacilli, agents in this family can not be beaten. All physicians are aware of the potential toxicity of these agents; it is therefore critical to specifically review their appropriate use.

The aminoglycoside family consists of five derivatives of *Streptomyces* species (to have the suffix *-mycin,* an antibiotic must be derived from *Streptomyces):* strepto*mycin,* neo*mycin,* paromo*mycin,* kana*mycin,* and tobra*mycin;* two derivatives of *Micromonospora* species: gentam*i*cin and netilm*i*cin; and a semisynthetic derivative of kanamycin (which doesn't entirely rhyme): amikacin. Spectinomycin is a related aminocyclitol useful only for treatment of gonorrhea in patients hypersensitive to penicillins and cephalosporins (2 gm intramuscularly once).[1]

The mechanism of antimicrobial action of aminoglycosides involves two key steps.[2] The first key step is uptake across the cell wall and cytoplasmic membrane into the bacterial cytosol. This is an active (energy and O_2 dependent) process involving the polyamine transport system. From this stem two key observations: (1) anaerobic bacteria do not possess this transport system and therefore are not susceptible to aminoglycosides, and (2) facultatively anaerobic organisms (and most bacteria we call aerobes are actually facultative anaerobes) are resistant to aminoglycosides under anaerobic conditions (i.e., in an abscess cavity). The second key step in aminoglycoside action is binding to the 30S ribosome. This binding is irreversible and autoinductive, inducing the polyamine transport system to transport in more aminoglycoside. The binding of the aminoglycoside to the 30S ribosome inhibits protein synthesis, probably by blocking polypeptide elongation and causing an increased frequency of misreading of the genetic code. The effect of aminoglycosides on susceptible organisms is bactericidal. The exact mechanism(s) of this bactericidal effect are unknown, because other antibiotics that bind to the 30S ribosome frequently exert only a bacteriostatic effect (e.g., tetracycline).[3]

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There are three mechanisms of bacterial resistance to aminoglycosides.[4] By far the most important clinically is the action of aminoglycoside inactivating enzymes. These are plasmid mediated and transferable. They are located in the periplasmic space of aerobic Gram-negative bacilli. They are aminoglycoside acyltransferases, aminoglycoside phosphotransferases, and aminoglycoside adenylyltransferases, which alter the structure of the aminoglycoside in such a way that the antibiotic can no longer bind the 30S ribosome. Over 20 specific enzymes have been described. Different aminoglycosides are susceptible to different enzymes; amikacin is susceptible to the least number of aminoglycoside-modifying enzymes. A second mechanism of resistance is decreased cell permeability. This, too, is clinically important: it is an important mechanism of aminoglycoside resistance in Gram-positive cocci and is an important mechanism of resistance to amikacin. This mechanism simultaneously confers resistance to all aminoglycosides. Finally, ribosomal mutations conferring aminoglycoside resistance have been described, but not demonstrated to be clinically significant.

An understanding of some pharmacokinetic and pharmacodynamic principles is critical to effective use of aminoglycosides.

Four aminoglycosides have limited modern usefulness and will each be discussed briefly. Streptomycin now has activity limited in usefulness for treatment of infections due to the aerobic Gram-negative bacteria to brucellosis, tularemia, and plague. It remains an important drug for treatment of tuberculosis and other mycobacterial infections. It is also useful in combination with penicillins or vancomycin for synergistic treatment of serious streptococcal and enterococcal infections. Enterococci should be tested in vitro for susceptibility to <2000 μg/ml of streptomycin to predict synergistic activity.

Neomycin has proven too toxic for systemic use but is still commonly used in topical antibacterial preparations (e.g., neomycin for *Enterobacteriaceae,* polymyxin for *Pseudomonaceae,* and bacitracin for Gram-positive bacteria). It is useful for treatment of hepatic encephalopathy (2 gm PO on the first day then 1 gm PO bid)[5] and for bowel decontamination before elective colorectal surgery (1 gm PO tid with 1 gm erythromycin base on the preoperative day).[6] Although only about 3% of an orally administered dose is absorbed, this is enough to contribute to toxicity in patients with severe renal impairment and/or in patients receiving a parenteral aminoglycoside.

Paromomycin is administered orally, is essentially nonabsorbable, and is limited in usefulness to occasional use as an intestinal amebacide. However, a recent report demonstrating activity of paromomycin in tissue culture against *Cryptosporidium parvum*[7] suggests we may be hearing more about this agent in the future.

Kanamycin is still used in some institutions in a surgical irrigant, although the efficacy of this is subject to debate. It should be remembered that about 5% of kanamycin is absorbed from serosal surfaces during irrigation. This again can contribute to toxicity.

So streptomycin, neomycin, paromomycin, and kanamycin are not quite dinosaurs, but are not now major components of antibacterial chemotherapy. The four aminoglycosides that have been the mainstay of therapy against infections due to aerobic Gram-negative bacteria are gentamicin, tobramycin, amikacin, and netilmicin. The remainder of this discussion will be essentially restricted to these four.

First, some comments about in vitro antimicrobial activity. As mentioned above, the major mechanism of aminoglycoside resistance is plasmid-mediated production of aminoglycoside inactivating enzymes. A consequence of this is that the patterns of aminoglycoside susceptibility or resistance vary epidemically within institutions. The most important rule, therefore, of awareness of aminoglycoside susceptibility patterns is "know your own house." Consequently, any tables of percent susceptibility from somewhere else that I could present are of little benefit. It is critical that each microbiology laboratory provides physicians at its institution with this data periodically.

We can, however, make a few generalizations about comparative in vitro antimicrobial activity within this group. Gentamicin is generally preferred among these for treatment of infections due to Gram-positive bacteria. A definite caveat here is the emerging problem of enterococcal resistance to gentamicin.[8] Among the aerobic Gram-negative bacteria, the greatest number of organisms will be susceptible to amikacin. For *Pseudomonas aeruginosa,* more organisms will be susceptible to tobramycin than to gentamicin, and for organisms susceptible to both, the minimal inhibitory

concentration of tobramycin will likely be less than that of gentamicin, by about one-half; the activity of netilmicin against *P. aeruginosa* is less than that of either tobramycin or gentamicin.

Based on these bits of information, principles of choosing among the aminoglycosides can be summarized as follows. Gentamicin should generally be used for synergistic effect for treatment of infections due to Gram-positive bacteria. If gentamicin resistance is prevalent in one's institution, then amikacin should be the primary aminoglycoside for treatment of Gram-negative bacillary infections. If gentamicin resistance is uncommon, gentamicin should be the primary aminoglycoside for economic reasons (gentamicin is dramatically less expensive than amikacin). For known or highly suspected *P. aeruginosa* infections, tobramycin is generally the aminoglycoside of choice unless one is at an institution where tobramycin-resistant *P. aeruginosa* infections are common; in that circumstance, amikacin should be primarily used.

An understanding of some pharmacokinetic and pharmacodynamic principles is critical to effective use of aminoglycosides. The low toxic/therapeutic ratio makes appropriate dosing critical to effective therapy without undue toxicity. Three general points about aminoglycoside pharmacokinetics help explain a number of clinical observations: (1) these are basic drugs and therefore are less active in an acidic environment; (2) these are polar drugs that are highly water soluble and poorly lipid soluble; (3) there is essentially no metabolism of aminoglycosides. Tissue distribution is therefore excellent into pleural, pericardial, or peritoneal fluid, mediocre into bile and bronchial secretions, poor into cerebrospinal fluid.

Dosing of aminoglycosides is critical. It has been demonstrated that antibacterial efficacy correlates best with peak serum concentrations[9] and that peak serum concentrations >10-12 µg/ml for gentamicin and trough serum concentrations >2 µg/ml are associated with higher ototoxicity and nephrotoxicity risks.[10] Both aminoglycoside preparations and pharmacokinetics in individuals are highly variable. Pharmacokinetic dosing of aminoglycosides is of demonstrated benefit.[11] Guidelines for aminoglycoside dosing in the absence of a pharmacokinetics service are presented in Table 1. Most patients require monitoring of serum levels. These are usually obtained "around" the third dose, because at this interval in most patients, relatively steady state kinetics have been established. The timing of obtaining these concentrations relative to an infusion of the aminoglycoside is critical: "troughs" should be obtained 0 to 30 minutes before a dose, "peaks" should be obtained 30 to 60 minutes after completion of an infusion. Within this range, kinetics of aminoglycoside elimination approach linearity. As an exaggerated example: a patient has a trough of 1 µg/ml, is given a dose, and has a peak level of 4 µg/ml. You want the patient to have a peak serum level of 8 µg/ml. Solution: double the dose. Had you wanted a peak of 6 µg/ml, the patient would need 1.5 times the dose, etc. The problem is a bit complicated by the fact that aminoglycosides have a slower second elimination phase: levels will creep up about 10% to 20% per week on long-term thera-

Table 1. Aminoglycoside Dosing Recommendations

- Must know height and weight to determine initial dose
- Initial "loading" dose in mg/kg dosing weight:

Gentamicin	1.5-2.0
Tobramycin	1.5-2.0
Netilmicin	2.0
Amikacin	5.0-7.5

 Dosing weight = ideal body weight + (0.4 x (total – ideal weight))[24]
 For men: ideal body weight = 50 kg + (2.3 kg/in over 60 inches)
 For women: ideal body weight = 45 kg + (2.3 kg/in over 60 inches)
- Must know serum creatinine (S_{CR}) to give second dose
- Determine creatinine clearance (Cl_{CR}) by method of Cockcroft and Gault:[25]
 For men: Cl_{CR} (ml/min/70kg) = ((140 – age in years) x (weight in kg)) / (S_{CR} x 72)
 For women: 0.85 x above formula
- Give subsequent doses equal to the loading dose in mg on the following schedule:

Cl_{CR} >70 ml/min/70kg	q8h
Cl_{CR} 40-69	q12h
Cl_{CR} 20-39	q24h
Cl_{CR} <20	Based on daily serum levels

- Monitor peak and trough serum levels "around" the third dose and adjust as necessary to achieve desirable levels:

	Peak	Trough
Gentamicin	5-7 µg/ml	0.5-1.5 µg/ml
Tobramycin	5-7	0.5-1.5
Netilmicin	5-7	0.5-1.5
Amikacin	10-20	5-10

py with stable renal function. Therefore, serum aminoglycoside levels should be checked approximately weekly in patients on protracted therapy. One other problem can be encountered: penicillins and aminoglycosides can chemically inactivate one another in vivo, particularly if high penicillin concentrations are achieved in patients with renal insufficiency.[12] Perhaps the best way out of this dilemma (usually detected by persistently inadequate aminoglycoside serum levels) is to switch to amikacin, the aminoglycoside least susceptible to this problem.[13]

It is well known that the major toxicity of aminoglycosides is nephrotoxicity.[14] The mechanism of aminoglycoside nephrotoxicity remains incompletely understood. Extensive accumulation of aminoglycosides occurs in the renal cortex, and glomerular dysfunction results. If enzymuria, a very sensitive marker of renal tubular injury, is used, essentially everyone is "injured" by a single aminoglycoside dose, although renal tubular dysfunction per se is very rare. The usual clinical definition of aminoglycoside nephrotoxicity is an increase of serum creatinine greater than 0.5 m/dL if initially <3.0 mg/dL, or an increase greater than 1 mg/dL if initially >3.0 mg/dL. By this definition, the incidence of nephrotoxicity from aminoglycoside therapy is from 8% to 26%. The mean onset of rising serum creatinine in patients treated with aminoglycosides is between the sixth and tenth day of therapy. Aminoglycoside-induced renal insufficiency is characteristically nonoliguric, but oliguric renal insufficiency can occur. Aminoglycoside-induced nephrotoxicity is believed to always be reversible. Risk factors for aminoglycoside-induced nephrotoxicity are a high initial peak serum level, liver disease (particularly obstructive jaundice), advanced age, high initial creatinine clearance, female sex, and the presence of shock.[10] An extensive literature exists comparing nephrotoxicity of the various aminoglycosides. It is my opinion that these differences have not been reproducible and are therefore minor, if existent at all.

Ehrlich's concept of a magic bullet is not being fulfilled by aminoglycosides.

The second major toxicity of aminoglycosides is ototoxicity.[15] These agents achieve high and persistent concentration in the endolymph and perilymph of the inner ear. Ototoxicity may be either vestibular or cochlear. The incidence of ototoxicity defined clinically is variously reported as from 1% to 22.3%. Risk factors for ototoxicity are duration of therapy, presence of bacteremia, a high BUN/creatinine ratio, peak temperature, liver dysfunction, and advanced age.[16,17] Netilmicin may be less ototoxic than other aminoglycosides.[18]

The third potential adverse reaction to aminoglycosides is neuromuscular blockade. This is due to depression of the sensitivity of the postsynaptic muscle membrane to the effect of acetylcholine. This results in a flaccid paralysis, which can involve the respiratory apparatus. Its incidence is increased with the use of curariform drugs and by concomitant hypocalcemia. It is reversible by infusion of calcium and cholinesterase inhibitors. Because of this effect, aminoglycosides should generally be avoided in patients with myasthenia gravis. Additional rare toxicities of aminoglycosides include drug fever, drug rash, and blood dyscrasias.

Having grappled with these details about aminoglycosides, it is time to deal with issues of their clinical use in the 1990s. I believe that most patients with serious infections due to *P. aeruginosa* should be treated with a β-lactam antibiotic in combination with an aminoglycoside. It has been shown that any clinically significant population of *P. aeruginosa* contains subpopulations of organisms resistant to β-lactam antibiotics and subpopulations resistant to aminoglycosides.[19] Therefore the combination is required to treat the resistant subpopulation to each drug, to prevent the emergence of that resistant subpopulation. I am not yet convinced by any data that either a double β-lactam combination including aztreonam or a β-lactam plus fluoroquinolone combination achieves this same type of "synergy." So serious *P. aeruginosa* infections are offered as one firm clinical indication for the use of an aminoglycoside.

However, *P. aeruginosa* is not a common pathogen in community-acquired infections or in patients in smaller community hospitals. So we need to honestly review some previous indications for aminoglycosides in which it may now be appropriate to not use an aminoglycoside. One such circumstance, which has been carefully reviewed,[20] is intra-abdominal infection. Recent data have confirmed and extended those authors' conclusion that an aminoglycoside does not appear absolutely necessary in empiric treatment of intra-abdominal infection, except in certain circumstances. Usage of an aminoglycoside is particularly justified in

patients at risk for infections with *P. aeruginosa* or *Enterobacter* species, such as patients with nursing home- or hospital-acquired infection, patients who have recently received broad spectrum antimicrobial therapy, and patients on immunosuppressive therapy. If aminoglycosides are not used empirically, cultures should be obtained carefully and reviewed carefully for the presence of resistant bacteria. Aminoglycosides have never been particularly therapeutically impressive in the treatment of Gram-negative bacillary pneumonia. For nonpseudomonal Gram-negative bacillary pneumonia, use of a β-lactam or fluoroquinolone may in fact be preferable to use of an aminoglycoside. Another typical aminoglycoside use has been as part of a combination regimen for empiric treatment of the febrile neutropenic patient. Although data must yet be considered relatively preliminary, it appears that certain double β-lactam regimens are empirically suitable for this situation as well.[21]

The fundamental problem is that aminoglycoside nephrotoxicity and ototoxicity remain inseparable from the antimicrobial effect of aminoglycosides. Thus Ehrlich's concept of a magic bullet is not being fulfilled by aminoglycosides. The usefulness and use of aminoglycosides are clearly in decline. Further development of aminoglycosides does not seem very likely. Dibekacin and sisomicin are clinically available outside the U.S., but there are no plans for development here. The development of other aminoglycosides such as fortimicin, seldomycin, sagamicin, verdamicin, butikacin, and propikacin has been basically curtailed. The future of the family perhaps rests in continued investigations of prevention of toxicity. The report that polyaspartic acid prevents aminoglycoside nephrotoxicity in experimental animals may be a start in this direction.[22]

At least one new aminocyclitol is currently being actively developed: trospectomycin. This agent has a broad spectrum of antimicrobial activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria and is currently in clinical trials.[23] This drug appears to hold promise for the future.

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Human Ehrlichiosis—An Overview

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Canine ehrlichiosis, previously thought to be restricted to dogs, has gained prominence in the human population since 1986. In the United States, human ehrlichiosis is a newly recognized disease ranging from a mild infection to a severe life threatening or fatal disease. Since antibody titers were found to be highest to *E. canis* in human ehrlichiosis patients, it was believed that *E. canis* or a closely related species was the etiologic agent. Investigators from the Centers for Disease Control recently have isolated a bacterium believed to be the etiologic agent of human ehrlichiosis and proposed the name *Ehrlichia chaffeensis*. Human cases of the disease have been identified primarily in the southeastern and south-central areas of the United States. Although relatively few cases are diagnosed, Oklahoma, according to one source, has been found to have the highest incidence rate. The human disease could be misdiagnosed as Rocky Mountain spotted fever, murine typhus fever, or Q fever.

Since 1986 a disease previously thought restricted to dogs has gained prominence in the human population. Canine ehrlichiosis due to *Ehrlichia canis* was first described by Donatien and Lestoguard[1] as a white blood cell–associated Rickettsia found in Algeria in 1935 and later reported elsewhere in Africa, the Middle East, and the Far East. First recognized in the Western Hemisphere in 1957 on the island of Aruba, this organism was subsequently found in Oklahoma dogs in 1963.[2] The microbial agent is a cause of canine illness that is characterized by fever, anorexia, weight loss, and bleeding. In the United States, human ehrlichiosis is a newly recognized disease ranging from a mild infection to a severe life-threatening or fatal disease.[3] Since antibody titers were found to be highest to *E. canis* in human ehrlichiosis patients, it was thought that *E. canis* or a closely related species was the etiologic agent in humans[4]; consequently, prior to 1984, the agent was regarded as a member of the genus Rickettsia. However, investigators from the Centers for Disease Control (CDC) have recently isolated a bacterium believed to be the etiologic agent of human ehrlichiosis and proposed the name *Ehrlichia chaffeensis*.[5] In the United States, cases have been identified primarily in the southeastern and south-central areas.[6] The only other Ehrlichia species isolated from human patients has been *E. sennetsu,* the causal agent of Sennetsu fever which is limited to Japan.[3]

Similar to Rocky Mountain spotted fever (RMSF), human ehrlichiosis apparently is transmitted by ticks, although a definitive vector or reservoir has yet to be identified.[4] As in RMSF, patients often present with an acute febrile illness, often exceeding 102.2°F. Other common symptoms of ehrlichiosis and RMSF include myalgia, headache, and nausea, but unlike RMSF, the rash in ehrlichiosis is usually fleeting and occurs in only about one-third of the cases.[7] Laboratory-based surveillance had identified 236 patients in 20 states since 1986,[5] but the count has recently increased to over 300 cases of human ehrlichiosis in the United States.[8] The severity of the disease in humans is variable but several deaths due to ehrlichiosis have been

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reported.[5,8] In 1992, three new cases of human ehrlichiosis were reported in Oklahoma, bringing the total number of serologically diagnosed cases to 13 since 1989.[9] Every ehrlichiosis patient in Oklahoma has had a history of tick exposure while in the eastern wooded areas of the state during the months of March and April.[8]

Diagnosis

Ehrlichia are obligate intracellular organisms that parasitize mononuclear or polymorphonuclear leukocytes. Diagnoses are based on identification of characteristic inclusion bodies in patients' leukocytes or finding a fourfold or greater change in antibody titers to *Ehrlichia canis* using the indirect fluorescent antibody (IFA) test.[10] Case definition requires a minimum antibody titer of 1:80 for specimens processed by the CDC and 1:64 for specimens tested by the Oklahoma State Department of Health.

The inability to culture *E. canis* in large quantities for use as an antigen for IFA testing has delayed study of this newly recognized disease of humans. Currently, a continuous canine macrophage cell line, DH82, is used to support the growth of a new isolate of *E. canis* established from the whole blood of a carrier dog in Oklahoma. Using this antigen, the IFA test was shown to have a specificity of 100% and a sensitivity of 87.5%.[11]

The kinetics of the antibody response to *E. canis* in humans seems to be similar to that in dogs. Ristic et al[12] found that in ten experimentally infected dogs, the earliest appearance of antibodies was 11 to 28 days after inoculation. Similarly, Dawson et al[11] found that most human patients tested by the end of the fourth week had seroconverted. The distribution of titers suggests that to obtain the required fourfold increase in titer, serum specimens should be collected as close as possible to the day of onset and again 2 to 4 weeks later. If the initial serum specimen is not collected until the fourth week after onset, and the convalescent specimen is collected 6 weeks later, the antibody titer may show a fourfold decrease. Previous investigations of human ehrlichiosis excluded patients who had serological evidence of infection with other tick-borne agents. Since some patients with serological evidence of infection caused by rickettsiae also may have had evidence of ehrlichiosis, it is possible that some patients with ehrlichiosis may have been incorrectly classified as having RMSF, murine typhus fever, or Q fever.

Clinical and Epidemiological Findings

Clinical and epidemiological findings among patients with positive tests for *E. canis* are summarized in Table 1. The outstanding features are fever (greater than 38°C), headache, myalgia, tick exposure, and tick bite.[10] The median maximum temperature recorded in patients was 39.9°C (range: 38.3° to 41.1°C), and laboratory abnormalities included marked leukopenia, thrombocytopenia, and elevated liver function tests.[15,16]

Table 1. Ehrlichiosis: Clinical and Epidemiological Findings

Variable	Percentage
Fever (greater than 38°C)	85
Headache	85
Myalgia	82
Nausea/vomiting	42
Rash (any)	20
Rash on palms and soles	8
Platelets <150,000/mm^3	47
Leukopenia <4,200/mm^3	38
Hospitalized	38
Tick exposure	81
Tick bite	74
Mosquito bite	48
Chigger bite	41
Own dog	63
Own cat	41

Adapted from Harkess, et. al.[10]

Potential ehrlichiosis patients initially contacted or visited their physician within a median of 4 days (range: 1 to 19 days) after onset of illness. Among these, 85% were hospitalized but ehrlichiosis was not considered as the initial diagnosis for any patient, and it was recorded as the final or discharge diagnosis in only 18%. Of those diagnosed with ehrlichiosis, the median interval from onset of illness to hospital admission was 7 days (range: 1 to 15 days), and the duration of hospitalization was also 7 days (range: 3 to 60 days). The median interval from onset of illness to complete return to normal activities was 38 days (range: 1 to 270 days).[15]

Most clinical reports of human ehrlichiosis have described infections of adults (median age: 42 years) (range: 4 to 82 years); however, some reports have indicated cases in children.[12,13,15] For 14 states reporting cases, age specific incidence rates per 100,000 per year were 0.040 for 0 through 14 years, 0.023 for 15 through 34 years, 0.072 for 35 through 64 years, and 0.078 for 65 through 84 years.[15] Patients hospitalized for 7 days or longer were significantly older than nonhospitalized patients or patients hospitalized for less than 7 days. The number of hospitalizations, the severity of the complications, and the long periods to full recovery indicate the seriousness of the disease, especially in older patients. Since the risk of clinical ehrlichiosis

Table 2. Geographic Distribution of Ehrlichiosis Patients*

State**	Number Tested	Number Positive***
Arkansas	8	4
Florida	12	1
Georgia	35	2
Kentucky	2	1
Louisiana	1	1
Maryland	10	1
Missouri	31	7
North Carolina	4	1
Oklahoma	138	6
South Carolina	56	1
Tennessee	75	4
Texas	19	4
Virginia	26	6
Wyoming	1	1
Total	418	40

*Adapted from Eng, et. al.[15]
**States listed are those where patients were exposed to ticks, or if not exposed, the state of residence of the patient.
***Based on patients with a fourfold or greater change in antibody titer in response to *E. canis*.

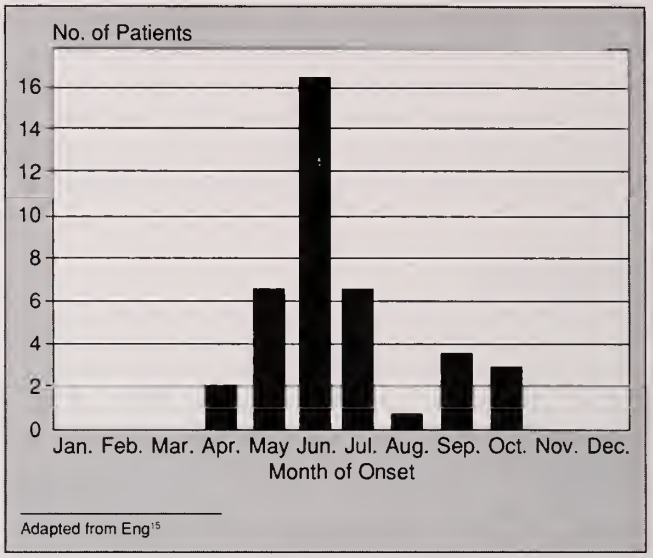


Figure 1. Ehrlichiosis—Monthly Distribution of Onset of Illness

appears to be greater in older persons, it is possible that age-related factors predispose older persons to exposure to the vector, to infection with the agent, to more severe illness, or to a greater likelihood of case detection.[15]

Among the diagnosed patients, 83% were male and except for two Native Americans and one black, all were white (non-Hispanic). As reported for other tick-borne diseases such as RMSF, it is likely that the larger population of male patients is due to the increased risk of tick exposure among males compared with females.[15]

According to Eng et al,[15] patients with ehrlichiosis resided in or were exposed to ticks in a total of 14 states including five states (Florida, Kentucky, Louisiana, Maryland, and Wyoming) where ehrlichiosis had not been reported prior to 1988 (Table 2). The states with the highest incidence rates per 100,000 persons per year were Oklahoma (0.19), Arkansas (0.17), Missouri (0.14), Virginia (0.10), Tennessee (0.08), and Georgia (.031).

Most patients (76%) first became ill between May and July, and none became ill from November through December (Fig. 1). Most patients (71%) resided in rural areas, and all but three reported a history of tick bites or exposure to ticks within a 3-week period (median incubation time: 7 days) before the onset of illness. Patients reported bites by "seed" ticks as well as adult-stage ticks and were exposed during recreational (39%), peridomestic (23%), occupational (19%), and military (10%) activities.[15]

Treatment

The treatment of choice for canine ehrlichiosis is tetracycline.[17] If this antibiotic is contraindicated, chloramphenicol also has been effective in treating human cases.

Conclusion

Human ehrlichiosis appears to be a rare disease in the U.S. The strong seasonality of disease onset and the large proportion of patients with a history of tick bite and rural residency support the hypothesis that human ehrlichiosis is primarily a tick-borne infection and, like other tick-borne diseases, appears to be increasing in Oklahoma.

The rarity with which physicians suspect ehrlichiosis probably reflects the rarity of the disease, a low level of awareness, the limited availability of a diagnostic test, and the breadth of clinical presentation. Physicians should consider the possibility of ehrlichiosis when patients have a febrile illness and seroconvert. Specimens in Oklahoma should be submitted to the CDC through the Oklahoma State Department of Health.

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COMMENTARY

Anencephalic Organ Donation in Oklahoma
Right Problem, Wrong Answer

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The scarcity of donor organs results in the death of some pediatric transplant candidates while they wait for an organ. The use of anencephalic infants has been suggested as a way to increase the donor pool. Advantages and disadvantages of this approach are reviewed, and recommendations made for the state of Oklahoma.

This past year in Florida, the parents of the infant Theresa Ann Campo-Pearson petitioned the state courts to declare her legally dead. They did this because she was born with anencephaly, a developmental anomaly characterized by the absence of the cerebral hemispheres and the cranial vault. A pregnancy resulting in an anencephalic infant is a real human tragedy—two-thirds of these infants are stillborn and the remainder are severely retarded with a life expectancy more often of days rather than weeks.[1] In order to salvage some good from their grief, Baby Theresa's family wanted her organs donated for transplant. They foresaw the need, but they could not foresee the problems.

The need for infant organ donors is unquestionable. In the United States there are an estimated 300 to 450 children with renal disease, 400 to 800 with liver failure, and 400 to 600 children with complex congenital heart disease who might benefit from organ transplant. Yet, the number of potential organ recipients far outweighs the number of available organs for infants and children; it has been estimated, for example, that 25% of those who require liver transplants die before receiving one.[2] It was with this tragic set of circumstances in mind that proposals to use the organs of anencephalic infants as donors have been made in the past, and it was with the same hope of finding some silver lining to their situation that Baby Theresa's family made a similar proposal.

Their offer came into a head-to-head conflict with Florida state law. Therefore, they have petitioned the court to change this law.[3] We should examine the reasons for the law and the arguments for and against change, with an eye towards similar changes in Oklahoma.

All states have enacted some formalized definition of death such as the Uniformed Determination of Death Act (UDDA). This act holds that an individual is dead if he or she "sustains irreversible cessation of circulatory and respiratory functions, or all functions of the entire brain including the brain stem" [Oklahoma Stat., Oklahoma Law, Title 63, Sections 3121-3123, 1986]. Baby Theresa was born without a cerebral cortex, but she was born with a living brain according to the law. As long as brain stem activity was present Baby Theresa could not be declared legally dead, nor could her organs be harvested for transplant purposes. Her parents asked the court for permission to declare her legally dead, and the lower courts refused. "Death is a fact, it's not an opinion,"

Related article, p. 107

Direct correspondence to G. Kevin Donovan, MD, Director, Warren Program in Bioethics, University of Oklahoma Health Sciences Center–Tulsa, 2808 South Sheridan Road, Tulsa, OK 74129.

stated the Broward Circuit Court.[4] This case is being appealed to the Florida Supreme Court even though Baby Theresa has already died. Those who are uncomfortable with "legislation by the judiciary" would have us consider changing the law before such a case is presented to the courts. Let us examine the arguments for and against.

The argument in favor in using anencephalic infants as organ sources appears simple and straightforward. These children are doomed to a short life, will never have a normal intelligence, and some good should be sought from their lives, if not for their own sake, then to provide some sort of comfort to their families. It has been argued that, in the face of a severe shortage of organ donors, anencephalics could fill this need. They are near enough to being brain dead that the use of their organs should make little difference to them nor should it matter much to the rest of us.

Let us examine these arguments and see if they are satisfactory:

The first issue is whether using anencephalic donors would significantly alter the deficit of infant organs available for transplant. As shown by Shewmon, et al, anencephalic organs would fall quite short of filling potential need. Ninety-five percent of the detected anencephalic fetuses are currently electively aborted; two-thirds of the remaining anencephalic infants are stillborn, and sightly more than half are premature, making them too small to provide transplantable organs. Not all of the rest could be expected to be offered as donors by their parents. Moreover, because of the disappointing experience in grafting infant kidneys, the recommended approach is to maintain small infants on dialysis until they reach several years of age, when the likelihood of successful transplant is much higher.

It has been assumed that the only significant malformation in anencephalic infants is in the central nervous system. In fact, around fifteen percent of anencephalic hearts, and an estimated twenty-five percent of the livers, will be unusable on the basis of malformation or hypoplasia. The final estimate was that between ten and twenty patients annually could benefit from the organs of anencephalic donors in the United States.[5]

There is another, more important concern. Even if a greater number of successful transplants could take place, we are faced with the question of whether to support these infants until a diagnosis of brain death can be made or to remove the organs without making such a determination. The recent experience at Loma Linda demonstrated the difficulties in making a diagnosis of brain death in anencephalic infants, given the paucity of verifiable criteria. They also were unable to harvest organs within the time constraints agreed upon.[6]

Baby Theresa's family wanted her organs donated for transplant. They foresaw the need, but they could not foresee the problems.

The only other alternative is to consider anencephalic infants as "nearly brain dead" or "brain absent." The obstacles in both promulgating and limiting such a definition seem obvious. For instance, the same criteria could be applied to a number of congenital malformations, and even persistently unconscious adults could be considered organ donors because they too are "nearly brain dead."

Clearly this would cause a tremendous professional and societal impact. In order to accept these circumstances for organ donation we would have to redefine the concept of brain death and alter its definition substantially. Even with the present definition, persistent confusion and mistrust among patients and their families exists when the topic of brain death is introduced. Such circumstances are always difficult; brain death is a concept whose primary utility occurs in ventilated patients with failing body functions who may or may not also be considered as organ donors. It is frequently difficult to explain that a brain dead patient is "truly dead," not "nearly dead" or "as good as dead." This confusion sometimes extends to health care professionals as well; there have been mistaken diagnoses of brain death with occasional reports of the patient "recovering." Moreover, what would be the impact on physicians and nurses as they watch organs being harvested from a "live, but as good as dead" infant?

This last point is probably the most cogent argument against pursuing transplantable organs from anencephalic infants. In order to do so,

we would have to be willing to alter not only accepted medical truths, such as the finality and verifiability of brain death, but also we would need to make a paradigm shift in our acknowledged obligations to the weakest and most vulnerable of our patients. To disregard the inconvenient fact that anencephalic infants are not yet dead, and to do this in order to derive some benefit from their existence, would be to use these infants as objects or means to an end, rather than an end in themselves. How could we do this without changing the type of people we are or the type of people we want to be? To become such a society as that would have a far greater and more negative impact than any number of unfulfilled requests for organ transplantation.

It is clear that the use of anencephalics as organ donors would require major shifts in medical science, philosophy, and social mores that would far outweigh any good to be done by the few successful anencephalic organ donations. Clearly, it is a goal not worthy of pursuing.

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The Author

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News

Todd and Painter

AMA officials planning to attend OSMA's Annual Meeting in April

Two top officials of the American Medical Association will visit Oklahoma for the OSMA Annual Meeting to be held Friday through Sunday, April 23–25, in Tulsa.

James S. Todd, MD, AMA executive vice-president, will address a joint luncheon of the OSMA and the OSMA Auxiliary on Friday at the Adams Mark Hotel, site of this year's Annual Meeting. Dr. Todd will update Oklahoma physicians on the AMA's role in health care reform and provide information on Washington's activities in the area of health care.

On Sunday morning, AMA President-Elect Joseph T. Painter, MD, a Houston internist, will address the Closing Session of the OSMA House.

Several meetings are scheduled at the Adams Mark Hotel in conjunction with the House of Delegates meeting.

The OSMA Board of Trustees will meet on Thursday afternoon, April 22.

The OSMA Hospital Medical Staff Section will hold a breakfast meeting at 7:00 AM Friday.

The OSMA Council on Rural Health also will hold a breakfast meeting at 7:00 AM Friday.

The Oklahoma Political Action Committee (OMPAC) will hold its annual meeting at 9:00 AM Saturday. All OMPAC members will be invited to attend. A new board of directors will be elected at the meeting.

In addition to business, a number of social activities will be held during the three-day meeting.

On Friday evening, the University of Oklahoma College of Medicine Alumni Association will have its annual awards dinner recognizing the private practice and academic physicians of the year. Also featured will be the presentation of the Amicus Medicinae Award.

The annual OSMA Presidents' Reception and Inaugural Banquet will be Saturday night. The evening will honor G. Lance Miller, MD, Tulsa oncologist, incoming OSMA president, and Mrs. Karen Mask, incoming OSMA Auxiliary president.

Guest speaker for the evening will be Robert S. Eliot, MD, director of the Institute of Stress Medicine International, Littleton, Colo. Dr. Eliot, a neurocardiologist, wrote *Is It Worth Dying For,* a book on stress that received the National Medical Writer's Award in 1986. His topic for the evening will be "Is There Life After Medical School."

OUHSC to host 'Horizons in Women's Health Care' conference

"New Horizons in Women's Health Care," a conference sponsored by the Department of Obstetrics and Gynecology and the College of Medicine Continuing Education Program at the University of Oklahoma Health Sciences Center in Oklahoma City, will be held Sunday through Thursday, April 4-8, 1993, at the Marriott Rancho Las Palmas Resort in Rancho Mirage, Calif.

The conference is designed for ob/gyn and family medicine physicians, nurses, nurse practitioners, and other health care professionals interested in contemporary issues in women's health care. The conference is approved for 18 hours of continuing education credit by the American Medical Association, and application has been made for CE credit from the American College of Obstetricians and Gynecologists.

Enrollment fee is $325 for physicians, and $225 for fellows, residents, nurses, and other professionals. The fee includes tuition, syllabus, breaks, continental breakfast, and pool party/Mexican fiesta. Discount airfares also have been arranged.

Conference topics will include: "Prematurity—Is It Preventable?" "Legal Issues—Cerebral Palsy: Res Ipsa Loquitur?" "Perinatal Care in Romania," "New Clinical Techniques in Prenatal Diagnosis," "Success or

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Cigarette smoking linked to 21% of state's 6,200 deaths in 1989

Cigarette smoking is the leading cause of preventable death and disease in Oklahoma, accounting for more than 6,200 deaths among Oklahoma residents in 1989, or 21% of all deaths in the state in 1989, the most recent year for which all data sources are available. Oklahoma ranks 10th in the nation for both lung cancer and stroke deaths, and 18th in the nation for deaths due to coronary heart disease; smoking is a significant risk factor for these diseases.

The Health Education and Information Service of the Oklahoma State Department of Health is studying the impact of smoking-attributable disease in Oklahoma using software and data provided by the Centers for Disease Control and Prevention, Office on Smoking and Health. This program, called SAMMEC, or Smoking Attributable Mortality, Morbidity and Economic Costs, uses mortality data, economic cost data, and smoking prevalence data for large populations to make calculations that assess the health and economic consequences of tobacco appropriate to the population.

To calculate smoking-attributable mortality for Oklahoma, the age-adjusted mortality rate was used to control for the differences in the age structure of the populations being compared. The age-adjusted mortality rate for Oklahoma in 1989 was 413.4 per 100,000 persons age 35 and older. The mortality rate was borne disproportionately by males; for males age 35 and older, the rate was 599.1 per 100,000 persons. The smoking-attributable mortality rate for females in the same age group was about one-half of that, or 249.4 per 100,000 persons.

The three leading causes of smoking-attributable deaths in Oklahoma in 1989 were cardiovascular disease (45.5%), cancer (34.2%), and respiratory disease (20.3%). Men and women had only slight differences in the distribution of these three causes:

	Male	Female
Cardiovascular disease	44.7%	46.8%
Cancer	35.8%	30.9%
Respiratory disease	19.5%	22.3%

As a measure of determining the relative impact of smoking-attributable disease in society, Years of Potential Life Lost (YPLL) were also calculated. YPLL are the number of years lost due to premature death from a smoking-related cause, calculated by subtracting a person's age at death from the average age the person could have been expected to reach if he or she had not died of a smoking-attributable cause. In 1989, 75,277 potential years of life were lost due to smoking. Of these years of potential life lost, 63.3% were lost among men and 36.7% were lost among women.

The Tobacco-Free Oklahoma Coalition, a statewide group of health professionals, business leaders, educators, and those involved in public policy, is working to educate Oklahomans about the health and economic effects of tobacco use. For more information, contact the Health Education and Information Service, 405/271-5601.

Health care conference *(continued)*

Failure of VBAC Can Be Predicted Using the Fetal Pelvic Index," "Prescribing Drugs for Medical Disorders During Pregnancy," "Biochemical Screening in Prenatal Diagnosis," "Complications of Anesthesia," "Substance Abuse in Pregnancy," "Infertility: I.V.F. Update," "Vestibulitis/Dyspareunia," "Hormone Replacement Therapy: What's New?" "Contraceptive Update," "Endometriosis," and "Reproductive Oncology: Prevention of GYN Malignancies—Laparoscopic Approach to Pelvic Masses." Case presentations and question-and-answer sessions also are scheduled.

Keynote speaker Dr. Calvin J. Hobel, director of Maternal-Fetal Medicine at Cedars Sinai Hospital in Los Angeles, will be discussing "Computer Assisted Problem-Knowledge Coupling."

For more information about the conference, call (405) 271-8717.

HIV/STD Service reports syphilis cases in state rise 47% in 1992

The HIV/STD Service of the Oklahoma State Department of Health received 705 reports of early (primary, secondary, and early latent) syphilis cases in 1992. This figure represents a 47% increase over 1991. The increase in congenital syphilis is even more worrisome: 26 cases were reported in 1992; a total of 14 cases were reported for 1991.

Timeliness of report is essential for disease intervention. Immediate reporting to the health department allows for our personnel to follow-up persons with reactive syphilis serologies quickly. If the report is of a

Syphilis reports *(continued)*

new infection, and you have not or will not be treating the patient, our staff will try to ensure that the patient is treated. We will also interview the patient to ensure than all sex partners are examined and treated either prophylactically or for infection as necessary.

If a patient presents with syphilis symptoms (a genital ulcer or rash), a serologic test for syphilis (RPR or VDRL plus a confirmatory test) should be performed. Stat RPRs and darkfield exams can be performed at the Oklahoma and Tulsa City County health departments and in some large hospitals. (Patients should be advised not to apply antibiotic or antiseptic solutions to lesions, as these may produce a false negative darkfield exam.) If these tests are negative or unavailable, and no treatment is given, the patient should be closely followed or referred to the local health department.

All pregnant women should be tested for syphilis at the first prenatal visit. If they are at high risk for syphilis (multiple sex partners, history of drug abuse and/or exchange of sex for drugs, or lack of prenatal care), they should be tested again during the third trimester and at delivery.

Appropriate treatment for early syphilis infection, as recommended by the CDC, is 2.5 benzathine penicillin IM. for those patients with a penicillin allergy, the alternate regimen is doxycycline 100 mg BID × 14 days. For pregnant women with a history of penicillin allergy, the CDC recommends skin testing of penicillin sensitivity, desensitization if needed, and treatment with benzathine penicillin. Erythromycin is no longer adequate therapy for syphilis in pregnancy.

Please report suspected syphilis infection to the HIV/STD Service at (405) 271-4636. If you would like a copy of the CDC Treatment Guidelines, or would like further assistance, please do not hesitate to call.

—Paul Zenker, MD, MPH
State Epidemiologist
Oklahoma State Department of Health

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Worth Repeating

Vertical integration:
■ What is it and what does it mean for physicians?

Vertical integration. The term surfaces in nearly every discussion about health system reform. Proponents of the community network reform concept tout vertical integration as an essential restructuring of the health system that will enhance quality of care and maximize efficiency. But what is vertical integration and what does it mean for physicians?

The concept of vertical integration originated in antitrust law and connotes agreements or relationships between entities at different levels in the chain of production or distribution. "Vertical" literally refers to the vertical relationship of one party to the other. A vertical diagram of the entities involved in producing medical supplies, for example, would place the supplier of raw materials at the top, followed by the manufacturer, the wholesaler, the retailer, and, at the lowest level, the consumer.

The antithesis of vertical integration is horizontal integration, which connotes agreements between entities at the same level of production. A classic example of horizontal integration is the merger of competitors, such as hospitals or competing physician groups.

As applied to health care, vertical integration means integration of the various entities involved in delivering health care in a geographic region—hospitals, physician practices, outpatient clinics, home health care providers, diagnostic laboratories, and other providers and suppliers of services and products. The stated goal is to maximize efficiency and enhance quality of care by delivering coordinated, centralized care in a system that is responsive to the community's needs.

The degree of integration between the various health care players can range from complete integration—where one entity acquires and subsumes another—to loose affiliations designed to meet specific goals such a increasing efficiency by combining billing functions or patient records. The literature abounds with examples of vertical integration on all points of the spectrum.

One of the most draconian approaches to vertical integration from medicine's perspective encourages hospitals to acquire physicians through employment specifically to control physicians' use of hospital resources while locking in patient referrals. The Health Care Advisory Bard, a Washington, DC, organization that represents hundreds of U.S. hospitals, issued a document in 1990 called "Competitive Strategy: 10+ Long-Term Strategic Positions for Hospitals." This 250-page document describes strategies for hospitals to "guarantee future revenue stream [and] improve margins in times of intense competition." The premier survival

From the January 1993 issue of the AMA's *Medical Staff Legal Advisor*. Submitted by William O. Coleman, MD, Chairman, Oklahoma State Medical Association Hospital Medical Staff Section.

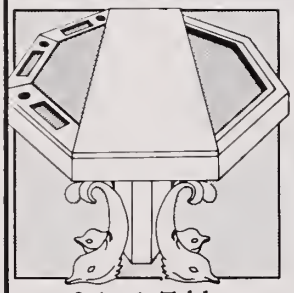
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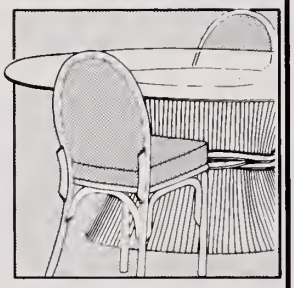
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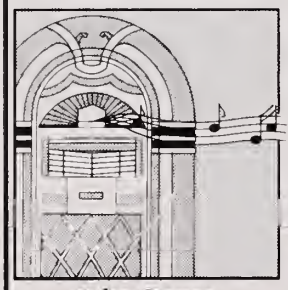
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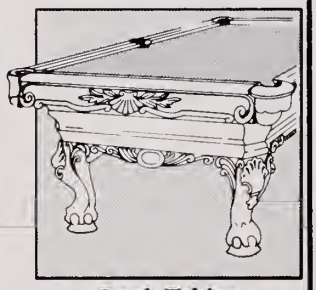

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Vertical integration *(continued)*

strategy, according to the Advisory Board, is to "control" physicians by employing them. As employers, hospitals can ensure referrals, limit utilization, and gain de facto control over payers. While acknowledging that this approach risks offending physicians, the Advisory Board "resoundingly" concluded that the risk is warranted.

The Advisory Board acknowledged that there are other approaches to ensuring long-term survival of hospitals, such as collaborating with physicians or encouraging physicians to acquire and operate hospitals. Neither of these alternatives offers as many advantages as employing physicians, the Advisory Board concluded, and "hospitals not in dire financial straits may find abdicating 100% of control to physicians too extreme a measure to stomach."

American Medical Association (AMA) members report that hospitals throughout the U.S. are increasingly following the Advisory Board's strategy. St. Luke's Medical Center in Cleveland, for example, has announced its intention to require all hospital-based physicians to become hospital employees. St. Luke's is pursuing this course despite assurances to the medical staff that if it endorsed a planned merger with a public hospital, the merger would not affect the staff's practice style. The hospital asserts that physician acquisition is necessary to allow competitive bidding for managed care contracts. St. Luke's situation is likely to be resolved through litigation.

Vertical integration does not necessarily have to focus on acquisition and control of physicians. It can be approached as a collaborative effort between partners. Four Denver hospitals and their physician organizations, for example, rejected a merger but formed a new entity to create new ventures. Two Indianapolis hospital systems recently announced formation of a joint task force to eliminate duplication of services and reduce costs. The Mayo Clinic acquired its first physician practice early in 1992 and established a regional practices board to develop relationships with other groups. Since then, Mayo has take other steps to create integrated healthcare systems.

Vertical integration can mean opportunity for physicians. Some physicians have determined that employment is the best choice for them and have sold their practices to hospitals. The Cleveland Clinic and a group of Indiana cardiologists have agreed to collaborate on educational, research, and consulting projects. Two large medical groups merged to form a "medical supergroup" of 380 physicians. A federal judge recently

approved a physician group's bid to buy a failing Chicago hospital. Members of the hospital's medical staff formed a limited partnership to acquire the hospital. Some entrepreneurial medical groups are pledging their revenue streams as collateral for bonds and using the proceeds to establish outpatient clinics that compete with hospitals.

Approaches to health system restructuring and vertical integration differ dramatically—and illustrate that vertical integration is a pluralistic concept. Although the negative approach of controlling physicians exists, vertical integration can present many opportunities for physicians to take the lead in restructuring local markets to meet the needs of the community.

The legal issues presented by vertical integration are complex and implicate many areas of the law, such as fraud and abuse, exempt organization tax requirements, state restrictions on the corporate practice of medicine, and corporate and employment law issues. The burgeoning activity in this area promises heightened government scrutiny. In a recent public statement, former Inspector General Richard Kusserow predicted that hospital purchases of physician practices will be one of two areas that receive the greatest government scrutiny in the 1990s.

How should physicians respond to vertical integration? Be aware of local efforts to integrate. Assess the opportunities for physicians to assume leadership roles. If a medical staff is resisting efforts to be "controlled," retain independent legal counsel to assist in developing a response and negotiating with the hospital without running afoul of the antitrust laws. Finally, ensure that independent legal counsel reviews all proposed agreements, such as an agreement to create a physician-hospital organization or other similar entity, prior to execution of the agreements.

The AMA is currently developing a program to inform physicians about developments in vertical integration and other aspects of health care reform, and to assist physicians to respond to these developments proactively.

PrairieSong

But for Winter

Spring is not,
But for winter ice.
Green alone
Does not suffice
To bloom again
What last was stone.
Who praises spring
Gives thanksgiving
For the frost
Who plunged summer
Into despair.
No land births
Whom winter does not
First prepare.

—Howard F. Stein, PhD
OU Dept. of Family Medicine

Deaths

David Lloyd Bell, MD
1941 - 1993

Tulsa physician David Lloyd Bell, MD, an orthopedic surgeon specializing in hand and carpal tunnel syndrome surgery, died January 23, 1993. Dr. Bell was born in Columbus, Kans., in 1941, and was graduated from the University of Iowa College of Medicine in 1967. He served for two years with the U.S. Air Force and was stationed at Blytheville Air Force Base in Arkansas just prior to his move to Tulsa in 1974.

Robert Charles Mayfield, MD
1924 - 1993

Robert C. Mayfield, MD, a 1950 graduate of the University of Oklahoma School of Medicine, died January 9, 1993, in Norman. Dr. Mayfield, a surgeon, was born in La Cross, Ark., and later that year moved to Norman with his parents. After completing his undergraduate work at the University of Oklahoma, he joined the U.S. Navy, serving 18 months with the naval amphibious forces in the Pacific. He returned to Oklahoma to earn his medical degree and established his surgical practice in Norman in 1954.

Maud Staveley-O'Carroll, MD
1927 - 1993

Maud Staveley-O'Carroll, MD, a native of Dublin, Ireland, and a 1959 graduate of the School of Psychiatry, Trinity College, University of Dublin, died January 16, 1993, in Oklahoma City. A psychiatrist, Dr. Staveley-O'Carroll joined the University Medical Center in Oklahoma City in 1970 after completing postgraduate studies in Tulsa and Vinita.



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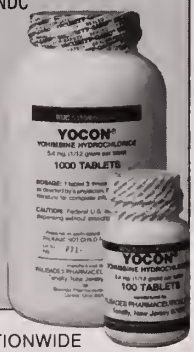
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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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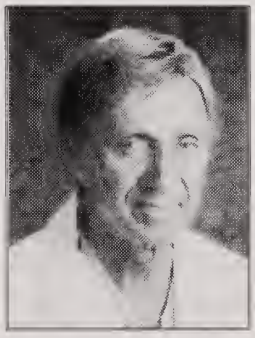
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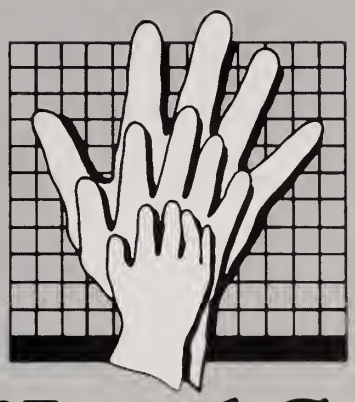
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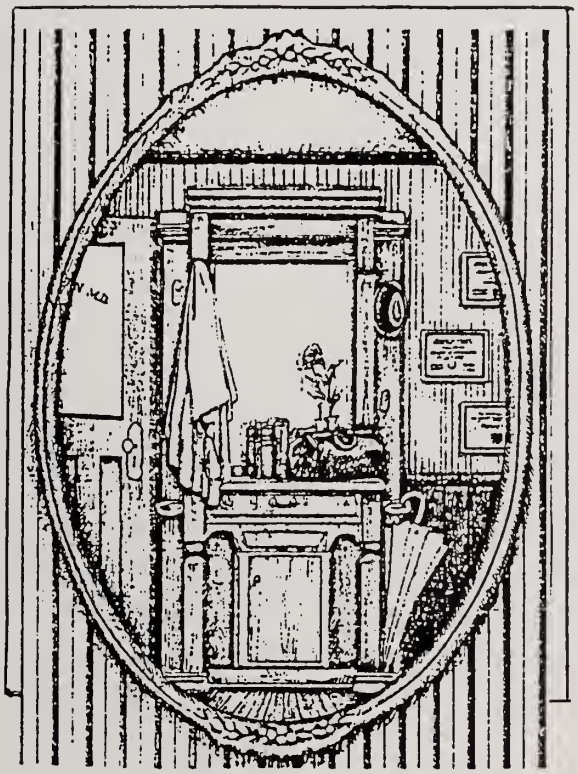
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Doctor's Day 1993

As we gather March 30, 1993, to observe Doctor's Day, let us remember the countless physicians who carry on the quiet work of healing each day in communities throughout the United States.

When we recognize our nation's physicians for their leadership in the prevention and treatment of illness and injury, let us remember the hard work, stress, and sacrifice not only of the physicians but of their families.

Doctors' Day is celebrated in many different ways. Scholarship or loan funds may be offered to medical students and equipment donated to hospitals and clinics. Auxiliaries sponsor blood drives, health fairs, career days in schools, and honor retired or retiring physicians.

Once again it is our hope that many communities will honor all physicians on this, their special day.

—Donna Hughes
1992-92 Doctors' Day Chair

The Last Word

■ **Mark Allen Everett, MD, was honored Janu**ary 28 at the ninth annual Evening of Excellence hosted by the University of Oklahoma College of Medicine Alumni. Dr. Everett received the Dean's Award for Distinguished Medical Service. A 1948 graduate of the OU medical school, Dr. Everett is a renowned clinician and researcher. After completing postgraduate studies in pediatrics and dermatology, he returned to Oklahoma City in 1957 to establish a private dermatology practice. He joined OU's medical school faculty in 1970 and was named head of the dermatology department, a position he still holds. Also honored at the Evening of Excellence was Paul H. Travis, Norman businessman and horse rancher, who received the Dean's Award for Dinstinguished Community Service.

More than 700 guests attended the formal gala, held at the Marriott Hotel in Oklahoma City. The event is a joint venture of the state's business and medical communities. Its goal is to raise research funds for the University of Oklahoma Health Sciences Center.

■ **Rochelle Ablah, MD, Oklahoma City, has been** nominated as the American Medical Association–Resident Physicians Section representative to the National Board of Medical Examiners.

■ **Lawton family physician Richard Brent** Smith, MD, has been appointed to the State Board of Health by Governor David Walters. With confirmation by the Oklahoma Senate, Dr. Smith will succeed Linda Johnson, MD. His appointment is for a nine-year term.

■ **The Pharmaceutical Manufacturers Associa**tion reports that 26 new drugs won approval from the Food and Drug Administration in 1992. Four of the drugs were approved for heart disease and/or hypertension (sotalol HCl, flosequinan, amlodipine besylate, bisoprolol fumarate), two for cancers (paclitaxel, teniposide), four for AIDS and AIDS-related conditions (zalcitabine, atovaquone, rifabutin, itraconazole), and one each for enlarged prostate (finasteride), arthritis (oxaprozin), and asthma (nedocromil sodium). Neuropsychiatric medications approved were treatments for migraine headaches (sumatriptan succinate injection) and depression (paroxetine HCl), a sleep aid (zolpidem tartrate), and a contrast agent for diagnosing central nervous system disorders (gadoteridol injection).

Other approvals were an anesthetic (desflurane) and a skeletal muscle relaxant (mivacurium chloride), three oral antibiotics (lomefloxacin HCl, temafloxacin HCl, cefpodoxime proxetil), a treatment for actinic keratosis (masoprocol cream), an oral contraceptive (desogestrel and ethinyl estradiol tablets), and an antifungal cream (tervinafine HCl). Holofantrine was approved for the treatment of multidrug resistant strains of malaria.

Additional information is available in the report "New Drug Approvals in 1992," available at no charge by writing New Drug Approvals in 1992, PMA, 1100 Fifteenth Street N.W., Washington, D.C. 20005.

■ **Resolutions for this year's Annual Meeting of** the OSMA House of Delegates, to be held April 23-25 in Tulsa, must be submitted on or before March 23, 1993. Any OSMA member, county medical society, or specialty society may submit resolutions for consideration and may obtain help in drafting those resolutions from the OSMA staff. Resolutions should be directed to the attention of House Speaker Larry L. Long, MD, OSMA House of Delegates, 601 Northwest Expressway, Oklahoma City, OK 73118.

■ **In Texas, anthrax, a disease that can quickly** kill animals, has been reported in a human. In the case reported by Jeffery P. Taylor, MPH; Dean C. Dimmitt, MD; John W. Ezzell, PhD; and Howard Whitford, DVM, PhD, a Texas ranch worker dissected several sheep that had died suddenly. The worker failed to use gloves or any other type of protection during the procedure. Several days after the dissections, the worker noticed a purplish lesion on his forearm, which became swollen and painful. The worker sought medical assistance when the swelling worsened and extended from the forearm to the elbow. Treated with penicillin, the worker recovered completely. The case was reported in the January issue of *Southern Medical Journal.*

■ **Richard Green, author of the Journal's Lead**ers in Medicine biographies since 1985, has been honored again for his work. In recent competition sponsored by the Oklahoma Chapter of the Society of Professional Journalists, Green was awarded first prize in the feature writing category for his biography of Dr. Claude H. Williams, published in January 1992. Another of Green's entries in that category, "The State of Adult Day Care in Oklahoma," [Journal, May 1992] earned a third place award. In competition sponsored by the Oklahoma City Chapter of the Public Relations Society of America, Green's biography of Dr. Robert G. Tompkins [April 1992] won first prize, known as the Upper Case Award, in feature writing.

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ONTRAINDICATIONS

ypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs uring pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. holesterol and other products of cholesterol biosynthesis are essential components for fetal development ncluding synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol ynthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may ause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contrain- icated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of child- earing age only when such patients are highly unlikely to conceive and have been informed of the otential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discon- ued and the patient apprised of the potential hazard to the fetus.

ARNINGS

ver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated th biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been ported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These normalities were not associated with cholestasis and did not appear to be related to treatment duration. In ose patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued om therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are ually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain ay also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. erum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., about six-month intervals). Special attention should be given to patients who develop increased transaminase vels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more quent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, en therapy should be discontinued. Persistence of significant aminotransferase elevations following discon- uation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see ONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). ch patients should be closely monitored, started at the lower end of the recommended dosing range, and ated to the desired therapeutic effect.

eletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been re- rted with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in avastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weak- ss in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy ould be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked vation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weak- ss, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if mark- ly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should o be temporarily withheld in any patient experiencing an acute or serious condition predisposing the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major rgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gem- ozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin ither with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients o were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with avastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to sculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving cebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: g Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated imen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment ntinued. **The use of fibrates alone may occasionally be associated with myopathy. The combined e of pravastatin and fibrates should generally be avoided.**

ECAUTIONS

neral: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). s should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homo- ous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase bitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying grees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacoki- cs of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC ues and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small mple size, the dosage administered, and the degree of individual variability, patients with renal impairment who receiving pravastatin should be closely monitored.

formation for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness weakness, particularly if accompanied by malaise or fever.

g Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARN- G: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of prav- atin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that a significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cyto- ome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after olestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been orted with another drug in this class. Patients receiving warfarin-type anticoagulants should have their pro- thrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

No interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid, or probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was used to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta- blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

Oncologic Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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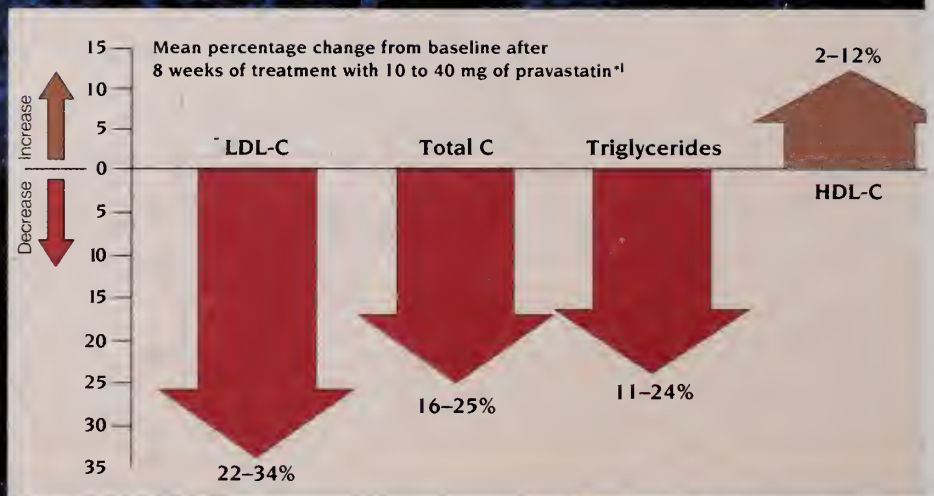
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Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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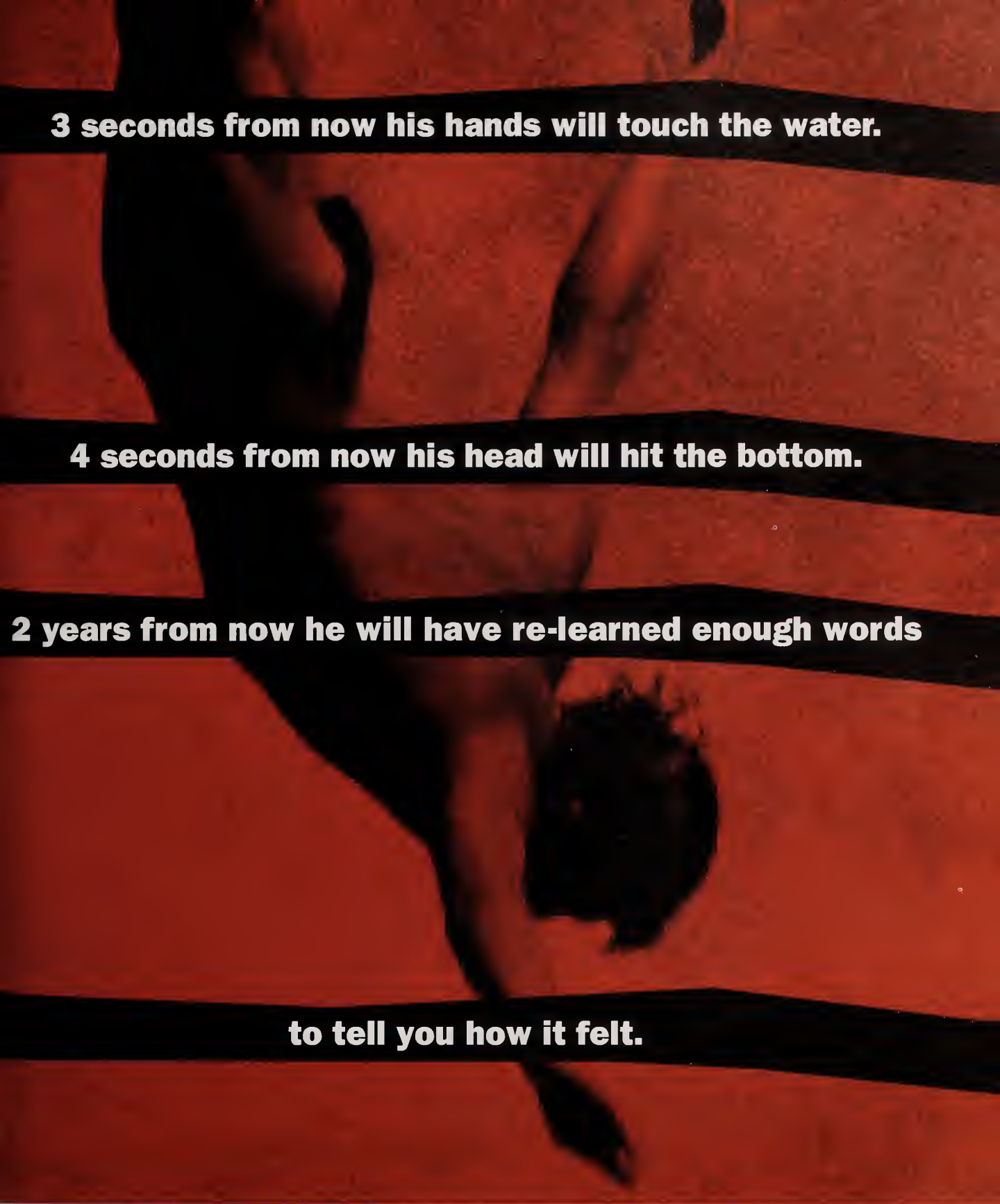
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Ray V. McIntyre, MD

Change!

Because lawmakers habitually resist unsolicited medical counsel, only once in a blue moon do physicians have an opportunity to affect the health policies of our society. Presently, however, the Oklahoma legislature has established a Health Care Study Commission to activate recommendations of the Commission on Oklahoma Health Care to the governor. New legislative initiatives on Oklahoma health problems are to be expected.

If the Oklahoma legislature functions responsibly in this endeavor, they will solicit both ideas and actions from the medical profession and the other professionals who treat Oklahoma citizens. Unfortunately, the power structure addresses health care problems primarily from the money angle, when the essential difficulty results from economic depletion, administrative haggling, and human behavior traits that no one dares to change.

Now is a time in Oklahoma development when the medical profession may be encouraged to be active in the discussion and implementation of basic changes in health care delivery in Oklahoma. The opportunity to project new ideas is now present. Everyone is aware that human behavior modification is a difficult task, but we also know that it *can* be done. The goal of a new triangular relationship between government, patient, and healer must be developed, now. A new therapeutic contract between the healers and the government patient must now be negotiated if the possibilities of modern medicine are to be fulfilled.

A necessity in today's health crisis is the development of an increased sense of individual responsibility for personal health choices in those patients who rely primarily on government programs for that care. The patient who pays directly for health care usually buys wisely, while the patient with an "insurance card" tends to care little about finances. Thus, if a "managed care" system for Medicaid patients would increase individual patient responsibility, the medical profession should encourage the change, so long as the individual physician can opt out of the system. Also, the removal of local Medicaid administration from the Department of Human Services is probably a necessary step in creating a system that most Oklahoma physicians would accept.

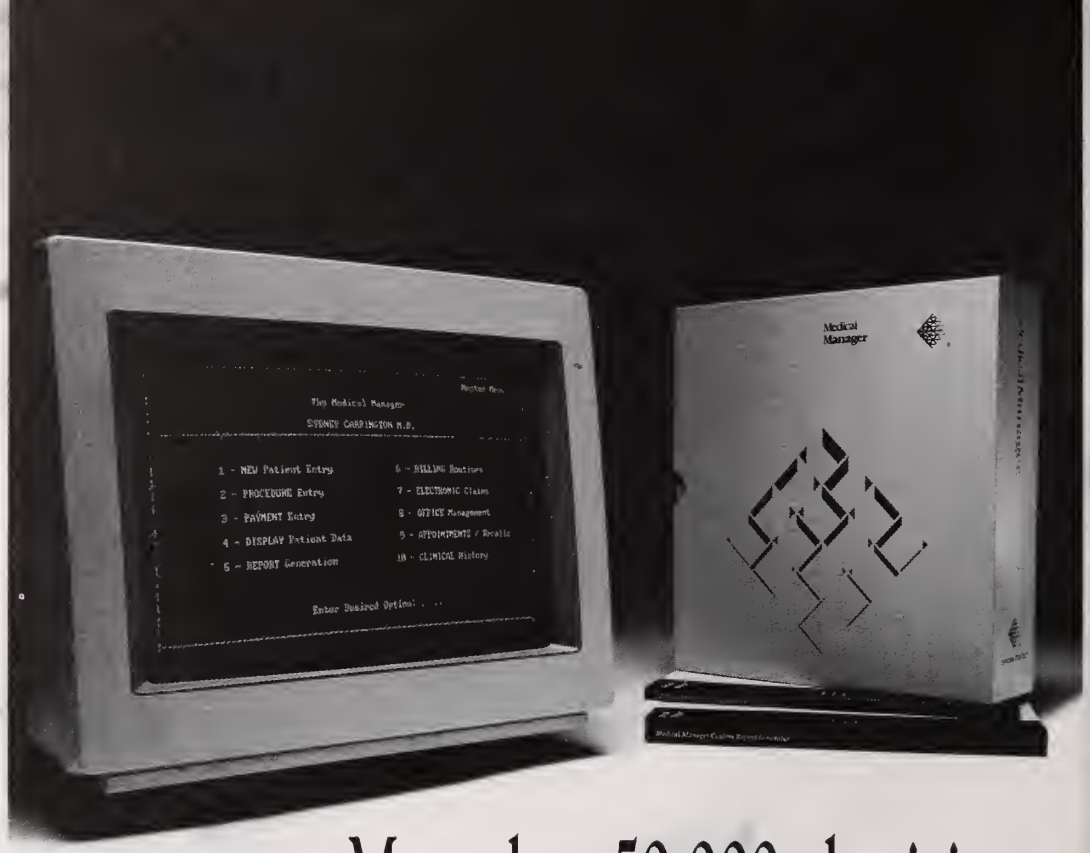
In a broader perspective, American society now must devise a new way to pay *individually* for medical care. The group insurance method has proven progressively faulty in the long run, adapts poorly to technical progress, and merely adds another expensive middle man between buyer and seller. Group insurance is always a declining balance game, as time must inevitably increase group expenses. As now used, insurance is part of the health care problem instead of part of the solution.

For coming generations, our society now needs to design an individual longitudinal and lifetime medical insurance account that accumulates funds during the individual's healthy and productive years in order to fund the expenses of the non-productive and unhealthy years. An individual medical care trust account should be created to replace group insurance methods.

In a time of change, it is appropriate for the medical profession to advance constructive ideas to our legislators. It is also time for change in the behavior of legislators, patients, and physicians.

Ray V. McIntyre, M.D.

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PRESIDENT'S PAGE

G. Lance Miller, MD

A Time of Transition



As I prepare to assume the reins of leadership by writing my first President's Page, I am torn between a desire to reassure our membership and an obligation to "tell it like it is."

For several years now we have been trying to prepare for the inevitable health care system changes we all know are necessary. Now the stage is finally set; the characters are chosen and already in the process of deliberation. Unfortunately, the administration in Washington has decided that input from Medicine is neither necessary nor desirable. So, we are left to wait and wonder about the fate of American medicine. This unpleasant and tragic circumstance has naturally created an atmosphere supercharged with anxiety and frustration among us all.

I can assure you that your association is expecting a concentrated effort, in concert with the AMA at the national level, to gain the support of as many members of this state's congressional delegation as possible. Thus, when the administration brings this issue to Congress, we hope to exert some degree of influence.

It is the opinion of many in organized medicine that the new administration is very focused on this issue and unwilling to tolerate divergent views. This, combined with a misguided sense of having a mandate, means that we are dealing with fanatical zeal, and we all must be prepared to swallow a "bitter pill."

Since there are many degrees of bitterness, perhaps the "pill" will not be too hard to swallow. I am concerned that many of us have not faced reality, preferring instead to immerse ourselves in the many responsibilities of our profession and trust that everything will turn out fine.

The leadership of OSMA strongly believes that it is the association's obligation to inform its members about perhaps the most important issue ever to affect American medicine. To that end your leaders and staff are assembling an outstanding cast of health care reform players to participate in a forum to be held during the 1993 annual House of Delegates meeting in Tulsa this month. Now is the time for every physician in Oklahoma to become informed on the issue of health care reform.

With reform will come new challenges to health care providers, as the techno-bureaucrats now want to call us. We must be the watchdogs over quality of care in the new system, something that has not been addressed in debates to date. We must find a way to place responsibility for quality where it belongs. We all will be expected to negotiate for our practice environment, i.e., financial remuneration, something few of us are qualified to do. We must be ever more watchful of onerous contract wording, again, not our strong suit.

With these and many other new problems and issues facing physicians, I have taken steps to look anew at what the association's goals should be and what programs and services should be developed to keep them current with members' needs in medicine's new era.

It is very likely that in a few months, when the legislative battle begins in Washington, we will ask each of you to join in the fray. Please respond promptly.

On the bright side, our state legislative efforts have been largely successful. It is clear, however, that we must continue to strive for more participation from the membership in order to strengthen our political action effort.

For the second year, we have enjoyed a unique coalition with the Oklahoma Bar Association in passing legislation. This year our non-partisan bill concerns liability caps for physicians who are practicing as volunteers.

Our Physicians Recovery Program continues to be a model for others and this year welcomed the participation of the Oklahoma Dental Association.

Through the efforts of Dr. Jay Gregory, the association continues to monitor the progress of practice parameter efforts nationwide.

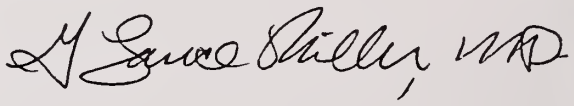
Dr. Lofty Basta's Council on Medical Education has done yeoman's duty the past two years and, as a result, the association has developed a highly effective program for CME certification.

Dr. Bernhardt's Council on Member Services has systematically evaluated numerous retirement investment plans and has recommended a truly unique and effective plan.

(continued)

By the time this page appears, your leadership will already have begun a review of all the association's existing programs to evaluate their necessity and effectiveness. I encourage each member to communicate opinions about our programs and services.

Finally, this association owes a debt of gratitude to Dr. James Funnell for a year of difficult decisions, steady control, and thoughtful management. Observing Jim in action this year has helped prepare me for the responsibilities of this important office. Be assured I take these responsibilities very seriously. I will do my best.



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Clinical Experience with HIV-Infected Patients at the University of Oklahoma Health Sciences Center: An Update

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We reviewed the course of 545 human immunodeficiency virus (HIV)-infected patients seen between 1983 and March 30, 1991. A majority were Caucasian homosexual or bisexual men, while parenteral drug abusers represented a smaller proportion than seen nationwide. In the 274 patients with the acquired immunodeficiency syndrome (AIDS), the distribution of AIDS-defining conditions was generally consistent with those reported in studies from elsewhere in the United States. However, toxoplasmosis remained relatively uncommon. There was a slightly higher incidence of disseminated histoplasmosis compared to other studies. HIV encephalopathy (AIDS dementia) was likely underdiagnosed. Although data suggested prolongation of the asymptomatic phase of HIV infection, median survival after AIDS diagnosis remained approximately 12 months.

During the past decade, the global pandemic of human immunodeficiency virus (HIV) infection and the acquired immunodeficiency syndrome (AIDS) has received increasing attention. Data acquired and published by the Oklahoma State Department of Health (OSDH) provide important information about the incidence of HIV infection and AIDS in our state, the demographics of infected patients, and the initial AIDS-defining condition of patients with AIDS. However, the spectrum of problems encountered in the longitudinal care of these patients is not fully apparent from such data. Additionally, some geographical variation in epidemiology and clinical presentation of HIV infection and AIDS has been noted. Our purpose is to continue to monitor and report the patient population and disease manifestations encountered in one of the largest populations of HIV-infected patients in Oklahoma.

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Methods

Patient case record forms have been compiled on all HIV-infected patients seen by the Infectious Disease Section at either Oklahoma Memorial Hospital or the Oklahoma City Veterans Administration Hospital since 1986.[1] Cases seen prior to 1986 were collected by retrospective review. These patients do not include pediatric patients or hemophiliacs who are primarily cared for by different physicians in our center. The case records were initiated with the initial physician contact and updated periodically with patient visits and hospitalizations.

This analysis is based on the 545 patients seen by us between 1983 and March 31, 1991. This series includes the 272 patients previously reported.[1] All have been identified as HIV-infected by either positive serology or by history of positive serology. Patients without a diagnosis of AIDS were considered to be symptomatic from HIV infection if they had one or more of the following: chronic lymphadenopathy at two or more extrainguinal sites of ≥3 months duration, unintentional weight loss of at least 10% of body weight or at least 15 pounds, chronic diarrhea of unexplained etiology of ≥3 months duration, oral candidiasis, cutaneous herpes zoster (shingles), oral hairy leukoplakia,

idiopathic thrombocytopenic purpura, memory loss, or otherwise unexplained peripheral neuropathy. All patients considered symptomatic by this definition would be classified as Group III or IV in the Centers for Disease Control and Prevention (CDC) classification.[2] Patients were classified with AIDS by the 1987-revised CDC criteria.[3] These criteria were applied retrospectively to patients who were seen prior to this revision of the surveillance case definition.

A survival curve was constructed by the Kaplan-Meier method with standard life-table analysis.[4]

Results

The number of new patients presenting with HIV infection increased annually at our center, except for 1989 (Fig. 1). After a relative plateau period from 1986 through 1989, there was a sharp increase again in new patients encountered in 1990. The number of new patients encountered between January 1, 1989, and March 31, 1991, equaled the number of patients encountered in the entire period from 1983 through 1988. Of the 545 patients in this series, 274 (50%) met the CDC definition for AIDS, 67 (12%) were symptomatic from HIV infection but did not fulfill the AIDS definition, and 204 (37%) remained asymptomatic at the end of the observation period.

Our patients presented at a mean age of 33 years (minimum of 17, maximum of 66). As shown in Figure 2, 95.2% of our patients were male. Also, as shown in Figure 2, our patient population consisted of a lower proportion of females than reported from throughout Oklahoma or the U.S.[5] However, increasing proportions of female patients were seen in 1989 and 1990: of the 26 women seen since 1983, five were seen in 1989 (5 of 86 total patients seen that year, or 5.8%) and nine (9 of 137 total patients, or 6.5%) were seen in 1990. Comparisons of the race of patients in our series with national surveillance data are presented in Figure 3.

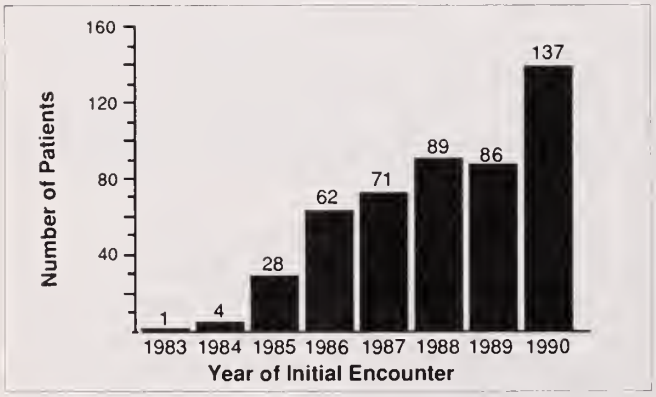


Figure 1. Numbers of new patients with HIV infection encountered by the Infectious Diseases Section of the Department of Medicine at OUHSC.

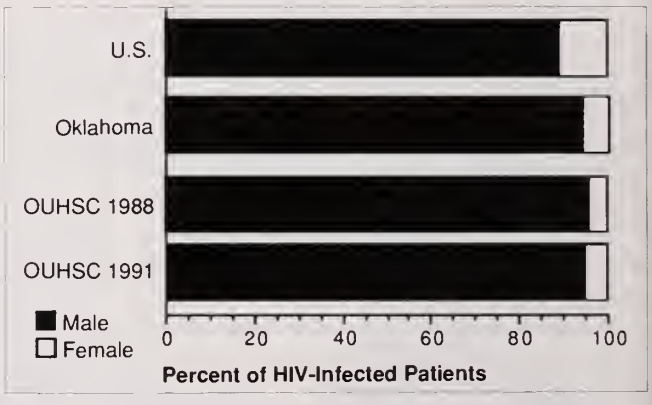


Figure 2. Sex of HIV-infected patients in this series (OUHSC 1991) compared to our initial report (OUHSC 1988),[1] Oklahoma State Department of Health data (Oklahoma) and national data from the Centers for Disease Control (U.S.).[5]

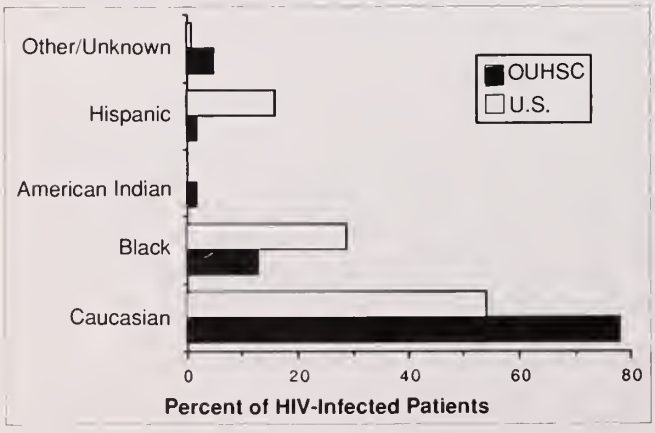


Figure 3. Race of HIV-infected patients in this series compared with U.S. national data from the Centers for Disease Control.[5]

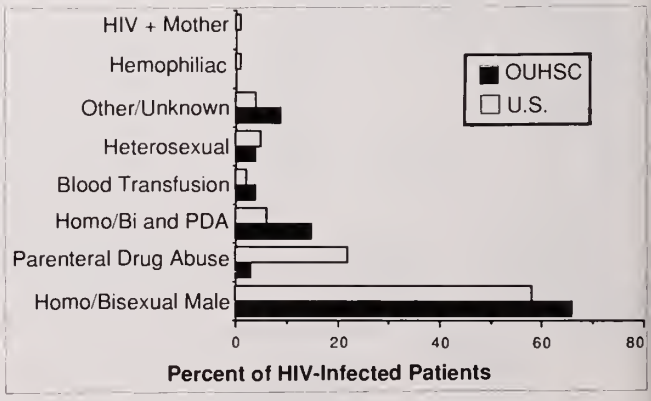


Figure 4. Risk factors for HIV infection for patients in the OUHSC experience reported here compared to U.S. national data from the Centers for Disease Control.[5] A hierarchical scheme for risk factor classification was used.

Our population was comprised predominantly of Caucasians (78%).

The distribution of risk factors for HIV infection among our patients is compared to the national data in Figure 4. Eighty-one percent of the patients in our group were either homosexual or bisexual males. Fifteen percent of these patients who were homosexual or bisexual males were also parenteral drug abusers. Only 3% of our patients were parenteral drug abusers who were not also homosexual or bisexual males. Sixteen (3%) of our patients were heterosexual partners of HIV-infected individuals, including 11 of the 26 females in this series. There were no health care workers or transplant patients without other risk factors. In 6% of our patients (24 males and 6 females), no risk factor was identified.

AIDS-defining conditions that occurred at any time during the course of disease are presented in Table 1, in order of decreasing frequency, and compared with other reported reviews.[6-16] *Pneumocystis carinii* pneumonia was the most commonly encountered disease, followed by esophageal candidiasis, HIV wasting syndrome, and Kaposi's sarcoma. We encountered proportionately more patients with histoplasmosis than has been reported in other cohorts, probably due to the endemicity of this organism in this area. We are likely underdiagnosing HIV encephalopathy, as judged by the relatively low incidence of this diagnosis being conferred in our cohort. We have not encountered any patients with multiple-drug-resistant tuberculosis.

The frequency of administration of various classes of drug therapies to this entire population of HIV-infected patients is shown in Figure 5. Zidovudine (Retrovir®), formerly azidothymidine or AZT) became the most frequently prescribed drug in this population. Other classes of drugs remained frequently prescribed in these patients.

Table 2 shows the distribution of outcomes at the end of this period of observation, based on the category of HIV infection. Of the 274 patients with AIDS, 10% were lost to follow-up and 56% were known dead. Survival from the time of diagnosis of AIDS is shown in Figure 6. Patients lost to follow-up were considered survivors until loss to follow-up and then were dropped from this analysis. Median survival from time of AIDS diagnosis was 12 months.

Table 1. Frequency of Occurrence of AIDS-Defining Conditions in This OUHSC Series and Comparison to Representative Reported Series from Other Centers.[6-16]

AIDS-Defining Condition	OUHSC (n=274)	Others
Pneumocystis carinii pneumonia	173 (63%)	63-85%
Esophageal candidiasis	60 (22%)	14-21%
HIV wasting syndrome	46 (17%)	14%
Kaposi's sarcoma	45 (16%)	16-40%
Disseminated atypical mycobacterioses	40 (15%)	3-28%
Chronic mucocutaneous herpes simplex virus infection	33 (12%)	4-29%
Cryptococcosis	31 (11%)	5-15%
Invasive cytomegalovirus infection, including retinitis	27 (10%)	7-40%
HIV encephalopathy	16 (6%)	30-65%
Histoplasmosis	13 (5%)	0-3%
Cryptosporidiosis	11 (4%)	5-18%
Central nervous system toxoplasmosis	11 (4%)	5-40%
Non-Hodgkin's lymphoma	7 (3%)	1-10%
Central nervous system lymphoma	6 (2%)	<6%
Progressive multifocal leukoencephalopathy	5 (2%)	2-6%
Disseminated herpes simplex virus infection	4 (1%)	<5%
Bronchial candidiasis	3 (1%)	<5%
Isosporiasis, coccidioidomycosis, salmonellosis	1(<1%)	<5%

Discussion

Compared to our initial reported experience with HIV-infected patients,[1] the percentage of patients with AIDS was essentially unchanged, the proportion with symptomatic HIV infection was decreased (from 27% to 12%), and the proportion of asymptomatic patients was increased (from 22% to 37%). These changes may simply have reflected biases in the ways patients were referred to our center. Alternatively, they may indicate that HIV-infected patients sought care at an earlier stage of infection or that earlier treatment of asymptomatic patients with antiretroviral therapy resulted in per-

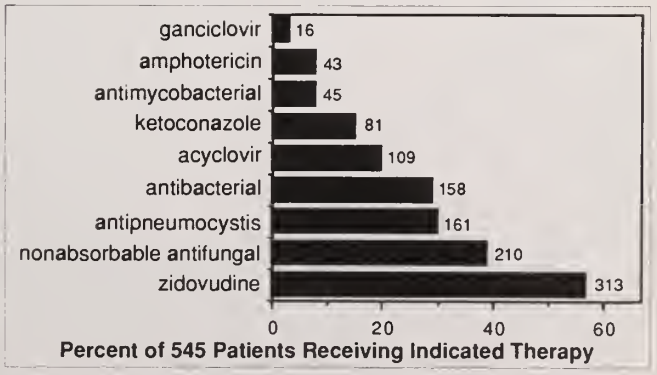


Figure 5. Administration of medications to HIV-infected patients. Percentage of patients receiving each medication is plotted and number of patients indicated at the right of each bar.

Table 2. Survival by Category of HIV Infection

Group	Asymptomatic	Symptomatic	AIDS	Total
Known surviving	143 (70%)	58 (86.6%)	93 (33.9%)	294 (53.9%)
Known dead	3 (1.5%)	3 (4.5%)	154 (56.2%)	160 (29.4%)
Lost to followup	58 (28.4%)	6 (8.9%)	27 (9.8%)	91 (16.7%)
Total	204	67	274	545

sistence of the asymptomatic state for a longer period of time.

There was little change in the demographics of patients we encountered with HIV infection. Our patients remained predominantly Caucasian homosexual or bisexual males. This may reflect lower numbers of parenteral drug abusers in our referral area, idiosyncracies in access to health care by parenteral drug abusers, and/or delayed institution of behavioral methods to limit the spread of HIV infection by Caucasian homosexual or bisexual males in our area.

The consistency in the distribution of AIDS-defining conditions from our first report[1] to this expanded series indicated little change in the frequency of presentation of these AIDS complications. A notable exception was the increased frequency in the diagnosis of central nervous system toxoplasmosis. We emphasized the low incidence of toxoplasmosis in our initial report, and, while our incidence of toxoplasmosis remained lower than some other reports, it increased to an incidence more in line with the majority of other reports.[11] There was some decrease in the frequency with which patients had chronic mucocutaneous herpes simplex virus infection and some increase in the incidence of cryptococcosis. Although only 6% of our cohort had a diagnosis of HIV encephalopathy (dementia) applied, our experience suggests that the actual incidence is considerably higher. The discrepancy may be the result of the requirements for such a diagnosis, which include both exclusion of other causes of intellectual dysfunction and assessment of intellectual function.

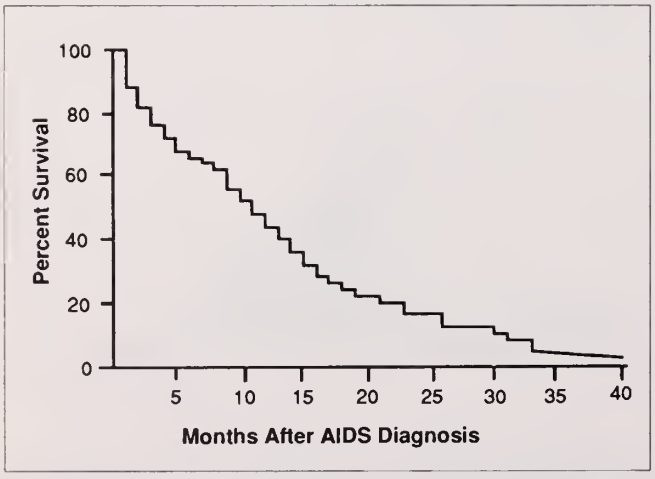


Figure 6. Survival from time of first diagnosis of AIDS for the 274 patients with AIDS.

There were significant changes in the pattern of administration of medications to the HIV-infected patients. Most notably, zidovudine became the most frequently prescribed medication in this population, now prescribed to 57% of patients in this series (increased from 26% in our initial report). This undoubtedly reflects its greater availability and use in asymptomatic patients with CD4+ cell counts <500/mm^3.

Somewhat surprisingly, the median survival of 12 months after diagnosis of AIDS was unchanged from that in our previous report. Our median survival is essentially identical to that reported in a larger cohort from New York City.[17] We are not able as yet to perform subgroup analyses of survival with AIDS by date of initial diagnosis, which may be required to demonstrate any improvement in survival in more recent cases. Nonetheless, although earlier antiretroviral therapy delays progression to AIDS,[18] and such therapy is now routine at our center, it appears that once the first AIDS-defining condition is recognized, median survival is still poor. This unchanged survival may also reflect the high number of medically indigent patients in our population; we continue to see a distressingly large number of patients whose first diagnosis of HIV infection is at presentation to our emergency rooms and clinics with a severe, AIDS-defining infection or malignancy. Their prognosis may not be as good as those who are diagnosed with HIV-infection earlier and managed systematically with antiretroviral therapy and prophylactic medications. One might hope that increased education and case finding, continuing evolution of improved therapies for opportunistic infections and malignancies, and improved antiretroviral therapy will have an impact on this poor prognosis of AIDS.

Conclusion

In summary, the Infectious Diseases Section of the Department of Medicine at the University of Oklahoma Health Sciences Center continued to see increasing numbers of new HIV-infected patients each year. Parenteral drug abuse remained uncommon as the sole

risk factor for HIV infection. There was only slight variance in the types of AIDS-defining conditions as compared to other cohort studies in the United States. The median survival after diagnosis of AIDS was 12 months, unchanged from our previous report.

Acknowledgments

The authors gratefully acknowledge the assistance of the many individuals who have provided care to these patients with us.

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Symposium on Antimicrobial Therapy
VII. The Fluoroquinolones

Ronald A. Greenfield, MD

This is the seventh of Dr. Greenfield's articles on antimicrobial therapy.

The quinolone family of synthetic antimicrobial agents began with nalidixic acid 30 years ago. It and its fellow first-generation quinolone, oxolinic acid, were not very impressive antimicrobials because of limited spectrum of activity, rapid development of microbial resistance, and at least some propensity to cause central nervous system side effects, including seizures. A second generation of quinolones, namely cinoxacin, pipemidic acid, rosoxacin, and flumequine, did not achieve much success either. However, a third generation of quinolones, the fluoroquinolones, have exploded onto the marketplace in the past several years and are now among the most commonly prescribed antimicrobial agents. There is great concern among infectious disease experts that much of this use is inappropriate and will lead to a limited span of usefulness of these valuable drugs by exerting pressure on the microbial biosphere to develop resistance. It is important to review what these agents are, when they *can* be used but probably *should not* be used, and when they *can* and *should* be used. These are the goals of this segment of this symposium.

Fluoroquinolone antimicrobial agents currently available in the U.S. are norfloxacin (Noroxin®), ciprofloxacin (Cipro®), and ofloxacin (Floxin®) (Table 1). Temafloxacin was briefly marketed in the U.S. as Omniflox® but the manufacturer has withdrawn this drug worldwide due to postmarketing reports of adverse reactions. The reports "included symptoms of severe hypoglycemia in elderly patients, hemolytic anemia, hepatic dysfunction, renal failure requiring dialysis in some instances, anaphylaxis, and death" (letter to physicians from Abbott Laboratories, 6/6/92). Further study of this matter is obviously required. Enoxacin (Penetrex®) has been approved by the U.S. Food and Drug Administration (FDA) but is not being marketed at this writing. Pefloxacin and lomefloxacin may be approved and released soon. Other fluoroquinolones in clinical trials include sparfloxacin, amifloxacin, fleroxacin, tosufloxacin, and rufloxacin. *Many* others have not yet been assigned a name that rhymes, but remain in the "alphabet soup" stage (e.g., WIN 57273). Fluoroquinolone proliferation in the next decade may exceed anything previously witnessed in antimicrobial chemotherapy. There are important differences among the fluoroquinolones, but overall, the similarities far outweigh the differences. In efforts to establish a foothold in the marketplace, more is often made of these differences than is really substantial.

Mechanisms of Action

The bacterial chromosome is a continuous circular strand of DNA that is about 1000-fold the length of the bacterium. Bacteria, therefore, must condense the chromosome. This is accomplished by supercoiling the DNA by the action of DNA gyrase. DNA gyrase is composed of two A subunits (encoded by the *gyr*A gene) and two

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B subunits (encoded by, you guessed it, the *gyr*B gene). DNA gyrase not only is responsible for maintaining supercoiling, but plays a critical role in DNA replication, repair, and transcription. As the main mechanism of action, the fluoroquinolones inhibit the A subunit of DNA gyrase.[1] As a consequence of this inhibition, the bacterial DNA does not maintain its supercoiled structure, the DNA backbone is cleaved, and both RNA synthesis (required for protein synthesis) and DNA replication (required for bacterial multiplication) are inhibited. At low concentrations, this effect is bacteriostatic, but within concentrations achievable in humans, this effect is rapidly bactericidal. The mammalian homologue of DNA gyrase, topoisomerase II, is at least 100-fold less sensitive to inhibition by the fluoroquinolones than bacterial DNA gyrase.

Mechanisms of Resistance[2,3]

A first bacterial mechanism of fluoroquinolone resistance involves a chromosomal mutation at the *gyr*A locus. This alters the affinity of the A subunit of DNA gyrase for the fluoroquinolone. Mutations at *gyr*A were the main limitation of older quinolones; they are much less frequent with the fluoroquinolones, and tend to raise the minimal inhibitory concentration about 10-fold, with many organisms remaining susceptible even with this mutation. A second mechanism of resistance involves the *gyr*B locus, and a third involves porin proteins and affects penetration of the quinolone into the bacterium. Resistance to the fluoroquinolones occurs infrequently in most bacterial populations (circa 1 in 10^{11} bacteria) but about 1000-fold more frequently in *Pseudomonas aeruginosa* and *Mycobacteria.* These mutations affect sensitivity to all fluoroquinolones similarly. There is as yet no evidence of plasmid-mediated or other transferable resistance to fluoroquinolones. However, a historical review indicates this may take up to several decades of use before clinical emergence.[4] Similarly, there has been no description of microbial production of fluoroquinolone inactivating activity.

Table 1. The Fluoroquinolone Antimicrobial Agents

Norfloxacin (Noroxin®)
Ciprofloxacin (Cipro®)
Ofloxacin (Floxin®)
Temafloxacin (Omniflox®)
Enoxacin (Penetrex®)
Pefloxacin
Lomefloxacin
and many others

Antimicrobial Spectrum

The spectrum of in vitro antimicrobial activity of the fluoroquinolones is partially presented in Table 2.[3,5] Of course, no one can memorize the data in such a table. It is presented here to give the reader a sense of the spectrum of activity of these agents and an opportunity to discover similarities and differences among them. These are truly broad spectrum antimicrobial agents. Their primary activity is against aerobic Gram-negative bacilli. They also have activity against Gram-positive bacteria and several other classes of bacteria.

The activity of available fluoroquinolones against Gram-positive bacteria is *not* very impressive. Although all but norfloxacin have demonstrable in vitro activity against *Staphylococcus aureus,* rapid development of resistance to ciprofloxacin by methicillin-sensitive and methicillin-resistant *S. aureus* has been described.[6] Although ofloxacin appears to have the best antistaphylococcal activity of the available fluoroquinolones, it is likely that it also is vulnerable to microbial development of resistance; additional time in clinical use will be required to evaluate this. Thus several classes of antimicrobial agents are preferred over fluoroquinolones for infections due to staphylococci. Similarly, the fluoroquinolones do *not* have outstanding activity against streptococci and enterococci, compared to other classes of antimicrobial agents. Ciprofloxacin and ofloxacin did poorly in a mouse model of pneumococcal pneumonia.[7] Again, at the present time, there are several classes of antimicrobial agents preferred over the fluoroquinolones for treatment of streptococcal and enterococcal infections.

The most notable feature of the fluoroquinolones is their remarkably broad activity against aerobic Gram-negative bacilli. As shown in Table 2, the fluoroquinolones are expected to have excellent activity against the overwhelming majority of *Enterobacteriaceae: E. coli, Proteus, Klebsiella,* and *Enterobacter* organisms as well as some of the more difficult-to-treat members of this family, including *Citrobacter, Providencia,* and *Morganella.* The fluoroquinolones are usually active against *Serratia,* but this is less consistent. The fluoroquinolones have excellent activity against essentially all of the bacterial pathogens that cause diarrhea. They have good in vitro activity against *Haemophilus, Moraxella,* and *Legionella.* They possess activity against many *Pseudomonas aeruginosa* and even many *Xanthomonas maltophilia.* They therefore represent the first opportunity to treat *P. aeruginosa* infections outside the urinary tract with an oral agent. They have excellent activity against the meningococcus and gonococcus as well. As a general statement, on

Table 2. Representative In Vitro Antimicrobial Activity of Some Fluoroquinolones*

Organism	Norfloxacin	Ciprofloxacin	Ofloxacin
Gram-positive bacteria			
Staphylococcus aureus	6.3**	1.0	0.4
Coag.-neg. staphylococci	3.1	0.25	0.8
Viridans streptococci	16.0	2.0	2.0
Enterococcus faecalis	8.0	4.0	4.0
Streptococcus pneumoniae	16.0	2.0	2.0
Gram-negative bacteria			
Escherichia coli	0.12	0.03	0.12
Proteus mirabilis	0.5	0.13	0.2
P. vulgaris	0.4	0.06	1.6
Klebsiella pneumoniae	0.5	0.06	0.2
K. oxytoca	0.25	0.13	—
Enterobacter aerogenes	0.4	0.06	0.8
E. cloacae	0.4	0.13	0.1
Citrobacter freundii	0.5	0.13	2.0
C. diversus	0.2	0.13	0.4
Providencia stuartii	1.0	0.5	1.6
P. rettgeri	1.0	0.25	1.6
Morganella morganii	0.06	0.03	0.02
Serratia spp.	3.1	1.0	1.6
Salmonella typhi	0.06	0.02	0.06
Shigella species	0.06	0.02	0.12
Aeromonas hydrophila	0.03	0.02	0.03
Campylobacter jejuni	0.5	0.12	0.25
Vibrio species	1.0	0.02	0.01
Haemophilus influenzae	0.06	0.01	0.03
Legionella pneumophila	2.0	0.5	0.5
Moraxella catarrhalis	0.4	0.03	0.1
Pseudomonas aeruginosa	2.0	0.5	2.0
Xanthomonas maltophilia	4.0	2.0	3.1
Neisseria meningitidis	0.03	0.01	0.02
N. gonorrhoeae	0.06	0.06	0.01
H. ducreyi	0.12	0.02	0.03
Gardnerella vaginalis	16.0	1.0	2.0
Anaerobic bacteria			
Peptostreptococci	16.0	8.0	8.0
Clostridium difficile	128.0	16.0	16.0
Bacteroides fragilis	>128.0	8.0	8.0
Other bacteria			
Mycobacterium tuberculosis	8.0	1.0	1.3
M. fortuitum	2.0	0.3	1.3
M. avium complex	>16.0	16.0	10.0
Listeria monocytogenes	4.0	0.5	1.0
Mycoplasma pneumoniae	12.0	2.0	2.0
M. hominis	16.0	1.0	0.8
Ureaplasma urealyticum	32.0	4.0	1.6
Chlamydia trachomatis	25.0	1.6	0.8

*From references 3 and 5
**Values shown are 90% minimal inhibitory concentrations (μg/ml) reported from multiple studies.

purely a weight basis, the in vitro activity of ciprofloxacin against aerobic Gram-negative bacilli is the best of the currently available fluoroquinolones.

The fluoroquinolones have poor activity against the overwhelming majority of anaerobic bacteria; we will consider them no further for anaerobic infections. They have good activity against *Mycoplasma pneumoniae.* They also have good activity against the pathogens that cause nongonococcal urethritis/cervicitis: *Chlamydia trachomatis, Ureaplasma urealyticum,* and *Mycoplasma hominis.* They have moderate activity against *Mycobacterium tuberculosis* and *M. fortuitum.* They also have good activity against *Listeria monocytogenes.*

Before detailing the specific clinical usefulness of these antimicrobial agents, let us first review some aspects of pharmacokinetics, pharmacodynamics, and toxicity.

Pharmacokinetics and Pharmacodynamics

All currently available fluoroquinolones are available as oral preparations. The major pharmacokinetic parameters after oral administration of the available fluoroquinolones are shown in Table 3. With the exception of norfloxacin, oral bioavailability (% absorption) is very good. Norfloxacin in recommended doses achieves effective antimicrobial concentrations only within the urinary and gastrointestinal tracts and is therefore limited in utility to infections at these two sites. The half-life of ofloxacin is longer than that of ciprofloxacin, leading to a greater *a*rea *u*nder the serum *c*oncentration plotted versus time curve (AUC). An enterohepatic circulation leads to very high (circa 1000 µg/ml) fecal concentrations of norfloxacin and ciprofloxacin.[3] Urinary concentrations of fluoroquinolones vary from 20-fold to many hundred-fold simultaneous serum levels. Penetration of these agents into extravascular tissue sites generally is equal to or superior to other classes of antimicrobial agents. The fluoroquinolones achieve intracellular concentrations in human leukocytes of up to 10-fold simultaneous serum levels,[8] suggesting usefulness in treatment of infections due to intracellular pathogens. Dosage reduction of fluoroquinolones is recommended for moderate and severe renal impairment. The fluoroquinolones are not eliminated by either peritoneal dialysis or hemodialysis.

Ciprofloxacin and ofloxacin are available for intravenous administration as well as oral administration. For ciprofloxacin, an intravenous dose of 400 mg is approximately therapeutically equivalent to a 500 mg oral dose. The oral and intravenous dosages of ofloxacin are essentially equivalent, because of the excellent oral bioavailability of this agent.

The most important pharmacodynamic factor for the fluoroquinolones is the ratio of AUC to minimum inhibitory concentration (MIC).[9] Evidence is accumulating that a ratio greater than 10 is required for therapeutic efficacy. This ratio, therefore, serves as an excellent basis for comparison of predicted fluoroquinolone efficacy. This is likely a threshold phenomenon. It cannot be clearly stated, therefore, that a ratio of 20 is better than a ratio of 10, and it quite likely does not imply that one agent is twice as good as another in this situation.

There are important drug-drug interactions with which physicians prescribing these agents must be familiar.[10] Gastrointestinal absorption of the fluoroquinolones can be reduced due to chelation by concurrent administration of aluminum- or magnesium-containing antacids, oral preparations of iron, multivitamins containing zinc, or high-dose calcium supplements. Concurrent administration of sucralfate (Carafate®), which contains aluminum, also reduces absorption. These effects are independent of gastric pH; H_2-antihistamine agents delay but do not reduce fluoroquinolone absorption. All fluoroquinolones may reduce the metabolism of caffeine and theophylline, thereby increasing serum concentrations and accentuating dose-dependent effects. Of available fluoroquinolones, this is most common with ciprofloxacin and least common with ofloxacin, because (as can be inferred from the data in Table 3) ofloxacin is the least metabolized. It is also possible that the metabolism of cyclosporine (Sandimmune®), phenytoin (Dilantin®), and warfarin

Table 3. Pharmacokinetic Properties of Some Fluoroquinolones*

Property	Norfloxacin	Ciprofloxacin	Ofloxacin
Oral dose (mg)	400	500	400
Absorption (%)	35-70	75-85	70-80
Serum peak (µg/ml)	1.5	2.5	5.5
AUC** (mg · hr/l)	5.4	11.6	30
Urinary recovery (%)	25	30	90
Half-life (hr)			
Normal C_{cr}†	4	4	7
C_{cr}<10ml·min/1.73m²	8	10	30

*Adapted from reference 3
**Area under the serum concentration plotted vs. time curve
†Creatinine clearance

(Coumadin®) will be decreased by concomitant fluoroquinolone administration, and therefore that the therapeutic (and toxic) effects of these drugs will be augmented. Fortunately, theophylline, cyclosporine, and phenytoin serum levels can routinely be monitored, and the therapeutic effect of warfarin (the prothrombin time) can be directly monitored. There is evidence that the elderly and patients with liver dysfunction are particularly vulnerable to these effects. Additionally, there are reports of seizures in patients receiving enoxacin and fenbufen (a nonsteroidal anti-inflammatory agent, or NSAID). This is likely a rare event and more apt to occur with enoxacin, but clinicians should be cautious when prescribing any fluoroquinolone to patients taking any NSAID,[3] and should caution patients given fluoroquinolones about the use of over-the-counter ibuprofen.

Toxicity

Undoubtedly the excellent safety profile of the fluoroquinolones has contributed to their popularity. Overall, fluoroquinolone therapy has been discontinued due to adverse effects in only about 2% of patients.[2] There have not been substantial differences among the various fluoroquinolones in the propensity to produce adverse reactions. The most common adverse events have been gastrointestinal symptoms (3% to 6%) which have included (in declining order of frequency) nausea, abdominal discomfort, vomiting, and diarrhea.[2] Symptoms related to adverse central nervous system effects are the next most common (1% to 4%) and have included headache, dizziness, agitation, sleep disturbances and, rarely, seizures, delirium, and hallucinations.[2] Allergic reactions have been uncommon (0.5% to 2%): usually rash or pruritus; rarely fever, urticaria, angioedema, anaphylactoid reactions, and hypersensitivity vasculitis.[2] Transient elevations of serum aminotransferases (2% to 3%), transient mild leukopenia (0.2% to 3%), and eosinophilia (0.2% to 2%) occur infrequently.[2] Because of cartilage erosions in weight-bearing joints of some species of animals treated with fluoroquinolones, these drugs are not recommended for use in children or pregnant or nursing patients.

Clinical Uses

Because the primary activity of the fluoroquinolones is against aerobic Gram-negative bacilli, it follows that a primary usefulness would be in treating the infections most commonly due to these organisms, namely urinary tract infections. The fluoroquinolones have represented a marked advance in the availability of oral agents to treat complicated urinary tract infections (UTIs) and/or those due to multidrug resistant Gram-negative bacilli. Many studies have demonstrated that the fluoroquinolones are as effective as ampicillin or trimethoprim/sulfamethoxazole for treatment of UTIs (cystitis and pyelonephritis) due to susceptible organisms.[11] The key part of that statement was "as effective": there is no evidence that the fluoroquinolones are more effective than less expensive agents for the treatment of uncomplicated UTIs due to susceptible microorganisms, nor is the incidence of side effects convincingly less. Since most community acquired UTIs are susceptible to ampicillin or trimethoprim/sulfamethoxazole, reluctance to promote the development of resistance by microorganisms and cost factors indicate that the fluoroquinolones are *not* primary therapy for simple outpatient UTIs. Similarly, the fluoroquinolones have been demonstrated equal in efficacy to trimethoprim/sulfamethoxazole for the treatment of bacterial prostatitis due to susceptible organisms.[11] There is a single report of efficacy of norfloxacin for prophylaxis of recurrent urinary tract infections in women.[12]

The fluoroquinolones are useful for complicated (by structural or functional abnormalities) UTIs and/or nosocomial infections due to multidrug-resistant organisms. In such settings, they have demonstrated efficacy equal to parenteral antimicrobial agents.[11,13] In these situations their use is clearly cost effective. Recommended dosing for complicated urinary tract infections is norfloxacin 400 mg PO q12h, ciprofloxacin 500 mg PO q12h, ofloxacin 200 mg PO q12h, or enoxacin 400 mg PO q12h for 10 to 14 days. Longer duration of therapy at perhaps higher dosage is indicated for treatment of chronic bacterial prostatitis.

The fluoroquinolones have some usefulness for the treatment of sexually transmitted diseases.[14] Available agents are effective single dose therapy for urethral, cervical, rectal, and pharyngeal gonorrhea: norfloxacin is not approved for this indication but an 800 mg dose is effective; ciprofloxacin is not approved for this indication but doses of 250 mg to 500 mg have been effective; ofloxacin is approved and effective as a single 400 mg dose; a single 400 mg dose of enoxacin has been approved for this indication. It must be noted that the fluoroquinolones are *not* effective against concurrent syphilis; this is a definite *dis*advantage in treatment of gonorrhea in the public health arena. Although it is likely that fluoroquinolones may be effective in treating disseminated gonococcal infection or treating the gonococcal component of pelvic inflammatory disease, this is currently too inadequately studied to recommend any fluoroquinolone in either setting. None

of the fluoroquinolones is effective single dose therapy for nongonococcal urethritis/cervicitis.[14] Ofloxacin (300 mg PO q12h for 7 days) is as effective as doxycycline for treatment of nongonococcal urethritis/cervicitis. It is thus a more expensive alternative for this indication. All of the available fluoroquinolones have excellent in vitro activity against *Haemophilus ducreyi,* the causative agent of chancroid. Ciprofloxacin is the best studied agent in patients with chancroid; it appears to be an effective alternative to trimethoprim/sulfamethoxazole.[14]

The fluoroquinolones have excellent activity against the bacterial pathogens of diarrhea, as shown in Table 2. These include enterotoxigenic *E. coli, Shigella, Salmonella, Campylobacter, Vibrio, Aeromonas,* and *Pleisomonas.* As noted above, enterohepatic circulation results in high fecal concentrations of norfloxacin and ciprofloxacin, making these two agents particularly attractive in this setting. A number of studies have demonstrated the efficacy of norfloxacin and ciprofloxacin for treatment and prophylaxis of travelers' diarrhea.[2] Other studies have demonstrated the therapeutic efficacy of these agents for treatment of salmonellosis, shigellosis, and gastroenteritis due to *Campylobacter.* It is to be emphasized, however, that routine antimicrobial prophylaxis for all travelers is not recommended, and therapy for gastrointestinal bacterial infections is indicated only under specific clinical circumstances. Whom to treat is beyond the scope of this article, but it is again to be noted that there is significant concern about the promotion of the development of resistance to the fluoroquinolones by indiscriminate use of these agents for prevention and treatment of diarrhea, particularly diarrhea not confirmed as etiologically related to bacterial pathogens. Usual dosages are norfloxacin 400 mg PO q12h and ciprofloxacin 500 mg PO q12h for 7 days.

The fluoroquinolones are useful for prevention of Gram-negative bacterial infections in granulocytopenic patients;[15] infections due to Gram-positive bacteria become dominant when fluoroquinolones are used in this setting. *Helicobacter pylori,* which is associated with antral gastritis and peptic ulcer disease, is susceptible in vitro to the fluoroquinolones, but, like other antimicrobial agents, the fluoroquinolones do not appear to achieve ready elimination of *H. pylori* colonization/infection.[5]

Perhaps the greatest controversy surrounds the use of the fluoroquinolones for treatment of lower respiratory tract infections. The most important issues to recall in this matter are that up to 70% of lower respiratory tract infections in adults are caused by *Streptococcus pneumoniae* (pneumococcus), that the activity of fluoroquinolones against the pneumococcus is marginal, and that clinical failures of fluoroquinolone treatment of pneumococcal pneumonia have been documented.[3] Therefore, the fluoroquinolones are *not* recommended for empiric treatment of exacerbations of chronic bronchitis or pneumonia without further diagnostic evaluation. Although there are multiple reports in the literature of the efficacy of these agents in treating lower respiratory tract infections, this use is potentially hazardous and should generally be avoided unless it is documented that the pneumococcus is not involved.

These agents are useful for documented lower respiratory infections due to *Moraxella catarrhalis, Haemophilus influenzae,* or other aerobic Gram-negative bacilli. They may be useful for *Pseudomonas aeruginosa* lower respiratory tract infections, but combination therapy is probably required. Ofloxacin is active against *Mycoplasma pneumoniae,*[16] but clinical experience with treating this infection is as yet inadequate to recommend this use. Ofloxacin has been shown to be an effective alternative treatment regimen for *Chlamydia pneumoniae* (TWAR strain) infections.[17] Ciprofloxacin and ofloxacin are active against *Legionella pneumophila* (the causative agent of Legionnaire's disease), but again there is inadequate experience with fluoroquinolone treatment of legionellosis to enable recommendation for use in this setting.[3] Recommended doses for severe lower respiratory tract infections are ciprofloxacin 750 mg PO q12h and ofloxacin 400 mg PO q12h.

The use of fluoroquinolones for skin and soft-tissue infections has been reported, as reviewed.[2] It is to be noted, though, that most such infections are due to Gram-positive cocci, namely staphylococci and streptococci. As has previously been mentioned, the fluoroquinolones do not have impressive activity against these organisms. The fluoroquinolones have not been compared to first line agents for these infections and therefore should *not* be routinely used in this circumstance.[2] These drugs may be useful in complicated soft-tissue infections involving aerobic Gram-negative bacteria, such as presacral decubiti and infections of the feet of patients with diabetes mellitus and/or peripheral vascular insufficiency, usually in combination with other agents with better activity against Gram-positive and anaerobic bacteria.

The fluoroquinolones have an important role in enabling oral therapy, where previously frequently none existed, for Gram-negative bacillary chronic osteomyelitis in adults. It is quite difficult to critically evaluate the comparative antimicrobial efficacy of agents for the

treatment of chronic osteomyelitis due to the influence of multiple other factors on the chances for "cure" and the need for follow-up duration of several years to really achieve meaningful comparisons. However, it can be stated that, in general, ciprofloxacin and ofloxacin have compared favorably with standard parenteral antimicrobial agents for treatment of chronic osteomyelitis.[3] They would appear to be particularly useful in the long-term oral therapy of chronic osteomyelitis due to Gram-negative bacilli, after an "induction" course of parenteral antimicrobial therapy. Direct comparisons of fluoroquinolones with other oral antimicrobial agents for treatment of chronic osteomyelitis due to Gram-positive bacteria are not available; therefore this comparison remains entirely speculative. Generally, maximal doses of these agents are employed for treatment of chronic osteomyelitis.

As shown in Table 2, several of the fluoroquinolones have activity against several species of *Mycobacterium*. These drugs are not useful as single agents for any

Table 4. Role of Quinolones in Treatment of Specific Infections*

System Affected	Possibly Preferred Agent	Alternative Agent	Experimental Agent**	Agent with Little or No Role
Urinary Tract				
Uncomplicated infections		X		
Complicated infections	X			
Prostatitis		X		
Sexually Transmitted Diseases				
Uncomplicated gonorrhea		X		
Disseminated gonorrhea			X	
Chlamydial urethritis or cervicitis		X†		
Chancroid		X		
Pelvic inflammatory disease			X	
Syphilis				X
Gastrointestinal Tract				
Bacterial gastroenteritis‡	X			
Granulocytopenia§		X		
Respiratory Tract				
Acute exacerbations of chronic bronchitis		X		
Exacerbations of cystic fibrosis	X			
Nosocomial pneumonia		X		
Community-acquired pneumonia		X		
Community-acquired aspiration pneumonia				X
Legionella pneumonia			X	
Mycoplasma pneumonia			X	
Tuberculosis			X	
Meningococcal carriage		X		
Bone and Joint				
Osteomyelitis with Gram-negative bacilli	X			
Staphyloccocal infection			X	
Septic arthritis			X	
Skin and Soft-Tissue Infections		X		
Central Nervous System				
Bacterial meningitis			X	
Invasive external otitis	X			
Blood				
Gram-negative enteric bacteremia		X		
Pseudomonas bacteremia			X	
Staphylococcal bacteremia			X	
Streptococcal or enterococcal bacteremia				X
Anaerobic bacteremia				
Endocarditis			X	

*Adapted from reference 2.
**Requires additional study before use can be recommended.
†Ofloxacin is effective; norfloxacin and ciprofloxacin are ineffective.
‡Use should be limited to patients sufficiently ill that antimicrobial therapy would be considered on clinical grounds before a pathogen has been identified.
§Useful for prophylaxis of Gram-negative bacillary infections.

mycobacterial infection, because of the rapid development of resistance, but have utility in combination therapy regimens.[18] Ciprofloxacin and ofloxacin have been used in combination for infections due to multidrug-resistant *M. tuberculosis* and in therapy of *M. fortuitum* infections. Ciprofloxacin is part of a combination therapy regimen frequently employed for treatment of *M. avium-intracellulare* (MAI) infections in patients with the acquired immunodeficiency syndrome (AIDS); these infections are quite refractory to all forms of therapy.[19]

A final usefulness of the fluoroquinolones is for eradication of *Neisseria meningitidis* (meningococcus) from nasopharyngeal carriers. A single 750 mg dose of ciprofloxacin achieved success comparable historically to rifampin and minocycline.[20] Thus ciprofloxacin can be considered an alternate drug in this indication.

Summary

The fluoroquinolones represent an important addition to the antimicrobial armamentarium. They are, however, commonly overused. It is estimated that in 1989, ciprofloxacin was prescribed for 1 in every 44 Americans.[21] This observation demonstrates not only the overusage, but the economic incentive for development of additional fluoroquinolones. In some situations, oral fluoroquinolone therapy can reduce costs by eliminating the need for parenteral therapy and reducing the need for or the duration of hospitalization. In most situations where oral antimicrobial agents are being considered, however, the fluoroquinolones are among the most expensive alternatives. In addition to concerns about cost factors, it is important to reiterate concern that widespread overuse of these agents will promote the development of microbial resistance and ultimately limit their usefulness.

The clinical usefulness of the fluoroquinolones is summarized in Table 4.[2] As can be seen, the fluoroquinolones are the "possibly preferred agent" in very few infections: complicated urinary tract infections due to Gram-negative bacilli resistant to other oral antimicrobial agents, severe bacterial gastroenteritis, exacerbations of lower respiratory tract infection in patients with cystic fibrosis, osteomyelitis due to Gram-negative bacilli sensitive to the fluoroquinolones, and invasive external otitis. They are alternative agents in a number of other infections when sensitive Gram-negative bacilli are the identified pathogens. A considerable literature exists on using these agents in these and other circumstances, but one must remain wary of limited reports of efficacy in comparison to known efficacy of established and less expensive agents.

A recent review[3] listed some situations where a fluoroquinolone should *not* be used, and I wish to emphasize those here: otitis media or sinusitis when *Streptococcus pneumoniae* may be present, pharyngitis when β-hemolytic streptococci may be present, moderately severe community-acquired pneumonia when *S. pneumoniae* may be present, anaerobic bacteremia, seriously ill patients with staphylococcal or streptococcal bacteremia, and infections in children or pregnant women.

The bases for choices among the various fluoroquinolones are not as yet firmly established and are in very rapid evolution. At this writing (and subject to change before press time) there are not major cost differences between therapeutically equivalent doses of fluoroquinolones (i.e., differences are ≥20%). Norfloxacin is approved only for treatment of urinary tract and gastrointestinal tract infections. Enoxacin is approved only for treatment of gonorrhea and urinary tract infections. These limitations seem appropriate and only economic factors would make these agents preferred in any of those situations. Ofloxacin has an advantage for treatment of nongonococcal urethritis. Other differences are relatively minor.

The Future

The next decade will likely see marked expansion of the fluoroquinolone antimicrobial agents. New agents will offer once-a-day dosing, increased activity against Gram-positive bacteria, increased activity against anaerobic bacteria, increased penetration into cerebrospinal fluid and the central nervous system, reduced likelihood of drug-drug interactions, and possibly reduced toxicity. In short, this sounds like just about everything for which one could dream. The remaining unpredictable question, however, concerns the development and spread of microbial resistance to these agents. It is imperative for each physician to review his/her fluoroquinolone prescribing habits to achieve optimal patient outcomes while minimizing this risk. ℐ

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The Misuse of Cardiopulmonary Resuscitation

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Over a 41-month period, 1,233 "Code Blues" were retrospectively reviewed. Twenty-five codes on infants and children <16 years of age were eliminated from the study group. The adult survivors of 1,208 codes numbered 243 (20.1%). Clinical chart review revealed that 49 (4.0%) did not involve cardiopulmonary resuscitation (CPR) or intubation and were "non-codes." Of the remaining 1,159 codes, there were 194 (16.7%) survivors. Of these survivors, 102 (52.5%) were patients with respiratory distress or failure and required intubation only. No CPR was needed. Thus, only the remaining 92 survivors of the 1,057 codes were cardiac cases for which CPR was appropriate (8.7% survival). Ventricular tachycardia and fibrillation, promptly defibrillated, was the most important rhythm factor for survival. Underlying ischemic heart disease (acute myocardial infarction and chronic ischemic heart disease with arrhythmia) was the most common underlying disease entity among the survivors. CPR performed in the group of patients unlikely to survive was expensive.

The use of cardiopulmonary resuscitation (CPR) has become commonplace and often expected for all patients who suffer cardiopulmonary arrest unless do-not-resuscitate (DNR) orders are present. This practice has become routine in hospitals without a specific mandate from official bodies (such as JCAHO or state departments of public health).[1]

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In one state (New York), the law states that every patient is presumed to consent to CPR unless there is consent to the issuance of a DNR order.[2] The American Medical Association's Council on Ethical and Judicial Affairs, in its Guidelines for the Appropriate Use of DNR Orders, presumes the routine administration of CPR in discussing how and when CPR can be withheld.[3] More recently, federal law, the Patient Self-Determination Act, requires hospitals, nursing homes, and hospices to advise patients upon admission of their right to accept or refuse medical care and to execute an advance directive.[4] Furthermore, discussions on using or withholding CPR raise ethical issues, especially when there appears to be a general belief that resuscitation represents power over death in most cases. The discussions over the ethics of providing or withholding CPR are further compounded by lumping CPR with feeding and nutrition and other life-prolonging issues.[5]

Prior to the landmark report of Kouwenhoven, Jude, and Knickerbocker on closed chest cardiac massage,[6] patients who suffered cardiac arrest because of sudden unexpected electrical cardiac disturbance (usually ventricular fibrillation) were treated with direct cardiac massage. This often occurred in the operating room in the context of non-cardiac procedures and unexpected development of ventricular fibrillation. At that time, only direct cardiac defibrillation was possible.

The availability of closed chest massage to maintain circulation bought the needed time to bring the then newly available Zoll external cardiac defibrillator into use and thus restore normal sinus rhythm. It was for a

very specific purpose—reversing ventricular fibrillation (which meant death) in a patient who would otherwise not die, i.e., the patient was otherwise in reasonable health except for the unexpected ventricular fibrillation (in the operating room, usually anesthetic-related or because of reflex vagal stimulation brought on by traction on visceral organs).

The report of Kouwenhoven et al[6] was based on experimental animal studies wherein ventricular fibrillation was induced, and of the five clinical cases described, four were intraoperative anesthetic events and one was a case of acute myocardial infarction that developed ventricular fibrillation. It is unclear how this rather specific medical indication for the technique came to be applied for any and all types of medical conditions.

Because coronary artery disease, and specifically acute myocardial infarction, was a leading cause of death in adults in the U.S., and because the majority of these deaths were caused by potentially fatal electrical aberration in cardiac rhythm, the American Heart Association actively encouraged the use of CPR. The pulmonary component (ventilation) of cardiac resuscitation was a necessity to provide circulating blood with adequate oxygenation to prevent cerebral anoxia. In recent years, primary respiratory failure, requiring assisted ventilation has been arbitrarily lumped with CPR, further compounding the CPR issue.

Because of the above, and our perception that CPR was being inappropriately utilized in our institution, we decided to look more closely at our "codes." To recover the cases in which a "code" was called, we utilized our ECG log for "codes." At our institution, the ECG technician is always called as part of the "code team." The team is headed by the senior internal medicine resident for codes on patient floors, and by the emergency department staff physician in the emergency department. All the physicians and nurses who constitute the team are certified in advanced cardiac life support (ACLS) according to the standards set by the American Heart Association.

Method and Materials

Codes from October 1988 to February 1992 (41 months) were identified and the author reviewed the clinical records. The primary underlying disease was identified, and major associated medical conditions, the reason for the code, and the initial cardiac rhythm were noted. Among the survivors, every effort was made to also determine the time it took to restore normal sinus rhythm and cardiovascular stability. A successful code was defined as survival to discharge. Additionally, the hospital charges incurred by the unsuccessful codes for 12 months (October 1988 to September 1989) were obtained from the business office records to determine the cost incurred by the non-survivors from the day of "code" until demise.

Results

From October 1988 to February 1992 (41 months), a total of 1,233 codes were identified. When the infant and children codes (<16 years of age) were eliminated, a total of 1,208 codes remained, from which there were 243 survivors to discharge (20.1%) (Table 1).

Reviews of the clinical charts revealed that 49 of the 1,208 codes (4.0%) did not involve any CPR and were classified as non-codes. These were patients who developed hypotension secondary to blood loss, addisonian crisis, seizure disorders, anaphylactic shock 2° IV radiologic contrast, insulin-induced hypoglycemia, rapid atrial dysrhythmias such as atrial fibrillation, PAT, atrial flutter, morphine-induced respiratory depression reversed by naloxone hydrochloride, TIAs, cardiac tamponade post open-heart or secondary to pericarditis and treated by pericardiocentesis, and three cases of acute MI with left heart failure and respiratory distress relieved by a short period of ambu bag assist. In all these cases there was blood pressure, respiration, and pulse. When these "non-codes" are removed from the study, there remain 1,159 codes with 194 survivors (16.7%) (Table 1).

The review of the clinical data on the 194 survivors identifies two major categories of patients:

1. Patients having respiratory failure or distress from various causes as well as patients in coma from various causes and in whom the clinical decision to intubate was made. These patients had blood pressure and pulse. Dysrhythmia, when it occurred, resulted from hypoxia, and was corrected when adequate ventilation was restored. Of the 194 survivors, 102 (52.5%) were patients who required intubation only. By the strict definition of CPR, they were not true codes. Using a more

Table 1. Survivors to Discharge, All Adult Codes

Code	Total	No. Survivors	% Survival
All codes	1208	243	20.1%
Pulmonary & Cardiac codes only	1159	194	16.7%
Cardiac codes only	1057	92	8.7%

liberal definition, they constituted a pulmonary code rather than a cardiopulmonary code. If these cases are removed from the study group, there remains a total of 1,057 codes with 92 survivors (8.7%) (Table 2).

2. Patients with a life-threatening or potentially life-threatening rhythm disorder, i.e., ventricular tachycardia, ventricular fibrillation, slow heart rates such as profound sinus bradycardia, junctional rhythm, and complete heart block. There were no survivors among patients presenting with absolute absence of any rhythm (asystole). There were 92 patients in this group (Table 2) who could be classified by initial presentation into (Table 3):
 a. Ventricular tachycardia which required only cardioversion or lidocaine bolus treatment;
 b. Ventricular fibrillation reverting to normal sinus rhythm with the first defibrillation attempt and thus not needing the rest of the ACLS protocol;
 c. Ventricular fibrillation requiring several defibrillation attempts and thus also CPR;
 d. Slow heart rates resulting from vagal stimulation or high vagal activity; and
 e. Slow heart rates because of a sick sinus node, or complete heart block.

Table 2. Survivors to Discharge, Adults Only (n=243)

No CPR or intubation ("non-codes")	49	(20%)
Intubation only ("pulmonary codes")	102	(41.9%)
Cardiac codes	92	(37.8%)

Table 3. Survivors to Discharge, Cardiac Codes

Clinical Diagnosis	V.T. Cardioverted	V.F. Defib.	V.F. Defib. + CPR	Vagal S. Brady	Sick Sinus CHB
Acute MI	10*	19	10	0	2
Cor. art. disease	14**	13	2	4	4
Cardiomyopathy	0	1	0	0	0
Stab wound to left chest	0	1	0	0	0
No cardiac disease	0	0	0	5	0
Aortic stenosis	—	—	—	—	1***
Iatogenic 2 + verapamil	—	—	—	—	1
CHF in 79 yr. old (probably cad)	—	—	—	—	1

* Includes 1 spontaneous v.t. reversion to NSR without treatment, 3 v.t. reversion to NSR from lidocaine/pronestyle bolus only
** Includes 4 v.t. reversion to NSR: one from precordial thump and 3 from lidocaine
*** Includes junctional rhythm but responded to atropine only and like vagal

Characteristics of the 92 Survivors

A. Rhythm—
 70 were initially ventricular tachycardia or ventricular fibrillation (76%)
 22 were initially because of a slow heart rate (24%)
B. Underlying disease state—
 Ischemic heart disease (acute MI and coronary artery disease) = 83 (90.2%)
 Other = 9 (9.8%)
C. Sex (83 acute MI and CAD survivors)
 Males = 51 (71.4%)
 Females = 32 (38.6%)
D. Age (83 acute MI and CAD survivors)
 Age ≥70 = 47 (56.6%)
 Age <70 = 36 (43.3%)

The Non-Survivors

Of the 1,208 codes, 965 were non-survivors. Three hundred fifty-five were non-trauma cases in asystole upon arrival in the emergency department.

Despite CPR, 610 died in the hospital. Some of the underlying conditions were: acute myocardial infarction, post-operative state (open-heart), septicemia and bacterial infection, pneumonia, lung cancer, leukemia, pulmonary insufficiency (COPD), stroke, hepatic necrosis, multiple trauma, and pulmonary embolism.

The Cost

Utilizing hospital charges generated from the day of the code during a 12-month period (October 1988 through September 1989) there were 277 non-survivors. Thirty-five of the 277 survived 2 to 14 days after the initial code and incurred $909,463 in hospital charges. The remaining 242 expired in less than 2 days from the code and incurred $1,874,469 in hospital charges. The hospital charges for the 277 non-survivors totaled $2,783,932. This translates to an average cost per non-surviving code patient of $10,050.

Using the above figures, the estimated cost for 965 non-survivors is $9,698,250. These cost estimates do not take into account physician charges.

Survivors' Quality of Life

Four of the 83 acute MI/CAD survivors were resuscitated outside the hospital—3 at home and 1 at a park. In 1 of the 4, the patient went into

ventricular fibrillation shortly after paramedic arrival and was defibrillated immediately to normal sinus rhythm (NSR). The other 3 patients received citizen CPR prior to paramedic arrival when defibrillation was performed and ACLS protocols followed. The patient who was defibrillated immediately arrived in the emergency room in NSR and was discharged without sequelae. Of the 3 patients who initially had citizen CPR, 1 was discharged without sequelae. However, 2 were discharged to nursing home care in a vegetative state and with electrocerebral silence.

No complete follow-up regarding repeat cardiovascular events following discharge is available.

Discussion

Since the 1960 publication of Kouwenhoven, Jude, and Knickerbocker[6] on closed-chest cardiac massage, cardiopulmonary resuscitation (CPR) has been widely applied inside and outside hospitals. The original report was on 20 patients, with 14 alive at the time of the report (70% survival, presumably to discharge). Only 5 cases were reported in detail, and no subsequent report has approached this lofty survival-to-discharge survival rate. In 1985, the reported survival-to-discharge rate from the same institution was 14%.[7] Various reports on survival to discharge have varied within the same low range—5%,[8] 10%,[9] 14%,[10] 26%.[11] In studies specifically directed to the elderly, survival to discharge has been as low as 3.8%[12] and as high as 13.4%.[13] Out-of-hospital cardiac arrest and subsequent survival-to-discharge rate has varied from 2% to 26%.[14]

In the current study, noting all survivors to discharge, based upon the number of codes, yields a 20% survival rate, and even excluding the "non-codes," yields a 16.7% rate. The inclusion of all patients subjected to CPR without regard to their underlying disease is likely to be a major factor in the wide variation of percentage of survivors to discharge following CPR. Similarly, in the studies on the elderly, the variations in reported survival to discharge depend upon the underlying medical conditions. This is supported by the poor survival-to-discharge rate after CPR in a general medical ward (1%) compared to the ICU and emergency department (19%).[15] In the current study, when only patients with ischemic heart disease are considered, 56.6% of the survivors were age 70 or greater; this is consistent with the finding that when only the initial rhythm of ventricular fibrillation is considered, survival to discharge for the elderly (24%) is not substantially different than for a similar cohort of younger patients (30%).[16]

The current study also underscores the misleading increase in survival-to-discharge rate caused by the inclusion of primarily pulmonary or respiratory distress cases. Of our survivors to discharge, 52.5% required intubation only and not CPR, but materially contributed to the 16.7% survival-to-discharge rate from codes. Without the intubation-only cases, the percentage of survival from codes is only 8.7%. This substantial inflation of survival-of-codes rates by inclusion of respiratory arrest has also been noted by others.[11]

When the cases requiring intubation alone are excluded, it is striking that 90% of the remaining survivors had ischemic heart disease as the underlying medical condition. Of those patients, 76% had ventricular tachycardia or ventricular fibrillation as the rhythm associated with successful CPR. In other studies,[17] ventricular fibrillation is the first recorded arrhythmia of patients who have a sudden cardiovascular collapse. In only 1% was sustained ventricular tachycardia alone the presumed cause of collapse and unconsciousness.

In our cohort of cardiac survivors, 24 cases had ventricular tachycardia. One reverted to NSR spontaneously, 7 reverted to NSR following bolus dosing of lidocaine or pronestyl, and the rest were readily cardioverted. No actual CPR had to be performed.

Additionally, 32 patients who had ventricular fibrillation responded rapidly to the first attempt at defibrillation, again not requiring the full panoply of ACLS. Nine patients in ventricular fibrillation required the full-press ACLS protocol, but all responded rapidly. The longest duration of CPR required of these survivors was 13 minutes. Of the 3 patients requiring CPR, 2 had cardiovascular collapse at home and 1 collapsed in a public park. In all 3 cases, citizen CPR was initiated before paramedic arrival and defibrillation. The duration of CPR in these cases was not documented in the patient's hospital admission records. Two of these 3 cases were discharged to a nursing home in a vegetative state and with electrocerebral silence. One of the 32 patients responding to rapid defibrillation alone was also a patient who collapsed at home. However, ventricular fibrillation occurred while the paramedics were present and prompt defibrillation was possible. This patient was discharged without sequelae.

The review of clinical information on the cardiac survivors strongly suggests that ventricular tachycardia and ventricular fibrillation are the cardiac rhythms most favorable to survival to discharge following CPR. This is consonant with findings on "sudden death" in patients on holter monitoring. In those patients, most manifested frequent or complex ventricular contrac-

tion and in 65 of 72 patients (90.2%) was followed by ventricular tachy arrhythmia and subsequently followed by ventricular fibrillation.[18] These findings are in keeping with the original intent of CPR, i.e., to reverse a lethal arrhythmia in someone who otherwise would have survived. The most common cause of this arrhythmia is acute myocardial infarction in patients with ischemic heart disease or in patients receiving anti-arrhythmic drugs which are also pro-arrhythmic, and more recently, reperfusion arrhythmia in patients receiving a thrombolytic agent (Table 4).

The patients who developed a slow heart rate because of sinus bradycardia resulting from increased vagal tone, as in the context of an inferior myocardial infarction, are most likely to spontaneously correct to NSR or respond promptly to intravenous atropine. Complete heart block in the context of acute myocardial infarction responds to atropine if increased vagal tone is a mechanism, or if conducting tissue is affected, requiring electronic pacing. Slow idioventricular rhythm may be mistakenly classified as asystole and account for some of the reported survivals to discharge from asystole. None of our survivors was asystolic. The closest to it was the one case of acute MI developing complete heart block and periods of very slow idioventricular rhythm, resulting in absence of cardiac electrical activity for 30 to 60 seconds, thus causing Stokes-Adams episodes.

In patients without apparent heart disease who die of serious illness (stroke, hepatic failure, malignancy, septic shock, respiratory failure, severe electrolyte imbalance, acute pancreatitis), holter recordings performed to document terminal electrical events show a gradual slowing of heart rate and a shifting of the cardiac pacemaker from sinus node to atria, then junctional, idioventricular, and finally asystole. This was noted in 83% of cases vs. 17% who demonstrated terminal ventricular tachy arrhythmia. The mechanism of bradycardia and asystole is presumed to be due to generalized anoxic and toxic depression of the sinus and other subsidiary pacemakers.[19] It is likely that these are the cases we subject to CPR and meet with failure. It is also probably why their survival to discharge is dismal. It is all the more astounding that we should even consider subjecting such patients to CPR.

Table 4. Survivors to Discharge, Acute Myocardial Infarction

Total acute MI coded but died = 165
Total acute MI coded and survived = 56
Total acute MI = 221
Survival to discharge for acute MI = 25.3%

There were 965 non-survivors in this study group, and 355 were non-trauma cases declared dead in the emergency room. These 355 cases arrived in either asystole or electromechanical dissociation. In the distant past, prior to the extensive use of CPR, these patients would have been declared dead on arrival (DOA). At present, the public emergency response system institutes CPR and the patient arrives with full resuscitative efforts ongoing. The emergency department staff, in turn, feel compelled to continue these efforts further and may continue for 30 to 60 minutes before efforts are terminated.

The majority of the 965 non-survivors underwent CPR on the hospital patient floors. As indicated in the results, most CPR was on patients with serious medical illnesses and for whom a code was called for a terminal event because do-not-resuscitate orders were not present for a variety of reasons. The many reports on outcomes of cardiopulmonary resuscitation clearly identify that the severity of underlying illness, and having a rhythm disturbance resulting from an acute insult[20] (acute MI, drug induced, etc.), are important determinants of failure or success. Even in patients with acute myocardial infarction, survival following CPR does not always occur since factors other than rhythm disturbance may supersede in importance. The most common cause of early death in acute myocardial infarction is pump failure (62%), ventricular rupture (16%), complications of therapy (10%), and arrythmia in only 13%.[21] It is only in the latter group where CPR might be reasonably expected to have an impact.

The CPR attempts on the non-survivors are not without cost. As indicated in the results, the average cost per patient at this institution was $10,050. At a community hospital in Newport News, Va., the average cost for similar non-survival cases was $9,476 per patient. Additionally, this study[22] showed that their 33 crash carts were idle 99.9% of the time and that for the 21-month study period, personnel training costs, code blue participation, crash cart checking rituals and replacement, training equipment, and cost of postresuscitation care amounted to $2,352,771. Based on the number of their survivors to discharge (respiratory only 48%; respiratory failure and cardiopulmonary arrest 16.7%; ventricular fibrillation or ventricular tachycardia 20.9%; asystole 3.4%), the cost per survivor exceeded $60,000.

Our current study is heir to the disadvantages of any retrospective study. Hence, it is not possible to

determine the true salvage rate for acute myocardial infarction without knowing the total number of acute MIs treated at the medical center during the 41-month code study period. However, the 25% survival-to-discharge rate for acute MI cases subjected to CPR is positive and useful information. Similarly, comprehensive data on out-of-hospital resuscitative efforts were not available, and the 4 cases included in this report represent isolated events uncovered in the course of the clinical data review. Despite these intrinsic disadvantages, the data presented nevertheless highlight clinically useful information.

1. The current practice of reporting both primary respiratory resuscitative efforts and primary cardiac resuscitative efforts as CPR results in misleading and less-than-useful information. A clarification on usage of "CPR" terminology is needed.
2. A substantial percentage of survivors to discharge come from respiratory resuscitative efforts alone.
3. When cardiac resuscitation (true CPR) is performed, survivors to discharge are greatest when the rhythm is ventricular fibrillation or tachycardia, and this is most likely to be encountered in patients with acute myocardial infarction, patients with coronary artery disease having episodes of ischemia, patients on antiarrhythmic agents which can be pro-arrhythmic (e.g., Quinidine, Pronestyl, Norpace), and during reperfusion following thrombolytic therapy.
4. That the sooner defibrillation or cardioversion is done, the higher is the likelihood of success. In general, CPR efforts beyond 30 minutes are unlikely to result in survival to discharge.
5. That the current practice of performing CPR on all patients without a do-not-resuscitate order, regardless of their underlying medical illness, is not cost effective and not based upon scientific medical information.

For the clinician, the decision that a particular patient's condition deserves CPR because it is appropriate medical treatment can be difficult enough. It is compounded by the family's perception that "doing everything possible" should include CPR regardless of whether it is medically appropriate. Now, federal law through the Patient Self-Determination Act may foster the application of inappropriate CPR because the patient did not specifically indicate that it was not desired. Furthermore, the opposite dilemma can also occur, in that a patient who indicated that extraordinary measures are not desired may have in mind other issues of life prolongation such as ventilator use. In such patients for example, unexpected torsade and ventricular fibrillation because of quinidine medication should result in a good response to immediate defibrillation if the event is observed in hospital. Should this not be done because a DNR order is in effect? Most patients who fully understand the situation would likely choose to make the situation an exception, but such decisions need to be made in seconds or minutes if they are to be medically worthwhile. It would appear that there is no perfect solution and more documents, rules, and regulations do not take into account all possible scenarios. In the absence of anything better, an accurate diagnosis and good clinical judgment is still the best course of action.

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SPECIAL

Firearm-Related Mortality in Oklahoma, 1985–1989

Pamela J. Archer, MPH; Sue Makintubee, RN, MPH; Kristy M. Sells

To determine the extent of firearms as a cause of mortality, Oklahoma vital statistic records were analyzed. The annual mortality rate in Oklahoma between 1985 and 1989 was 20% higher than the U.S. rate. Firearms were the second leading cause of injury deaths; firearms were the leading cause of injury deaths among blacks and the leading cause of all deaths among blacks 15 to 29 years of age. Ninety-two percent of the firearm-related deaths were intentional; firearms accounted for 70% of suicides and 59% of homicides. The male death rate from firearms was 4.5 times the female death rate. Suicide rates were highest among white males 65 years and older; homicide rates peaked among black males 25 to 34 years of age. Residents of eastern Oklahoma had the highest rates. The magnitude and preventability of firearm-related deaths and injuries demand attention and collaboration from Oklahoma health care providers; public health, mental health, and education officials; and criminal justice professionals.

There are an estimated 100 million to 200 million privately owned firearms in the United States.[1,] More than 30,000 persons are killed by firearms each year in the U.S., making gun injuries the eighth leading cause of death.[3] Firearms rank second behind motor vehicles as the most common cause of injury death,[1,4-6] and are the leading cause of intentional injury death, accounting for more than half of all suicides and homicides.[4,7] The firearm mortality rate among males is more than five times the rate among females; persons 25 to 34 years of age have the highest rate, and the rate among blacks is more than twice the rate among whites. In fact, it has been estimated that a young black male has a 1 in 21 lifetime chance of being killed, most likely by one of his contemporaries.[8]

Recent articles show an association between firearm availability and subsequent suicide among adolescents.[9] The Oklahoma Behavioral Risk Factor Surveillance System reports that 50% of Oklahoma households own one or more functional firearms. In order to determine the descriptive epidemiology and magnitude of firearm mortality among Oklahoma residents, data on firearm deaths occurring between 1985 and 1989 were analyzed.

Methods

A firearm-related death was defined as that of a person who was coded with one of the following International Classification of Disease (9th Revision, ICD-9-CM) external codes (E-codes): 922.0-922.9, 955.0-955.4, 965.0-965.4, 970, 985.0-985.4. U.S. data/rates were based on 1987 firearm deaths reported by the National Center for Health Statistics. Oklahoma firearm deaths were abstracted from Oklahoma State Department of Health Vital Statistics data. All rates are annual and calculated per 100,000 population using 1980 census data.

Results

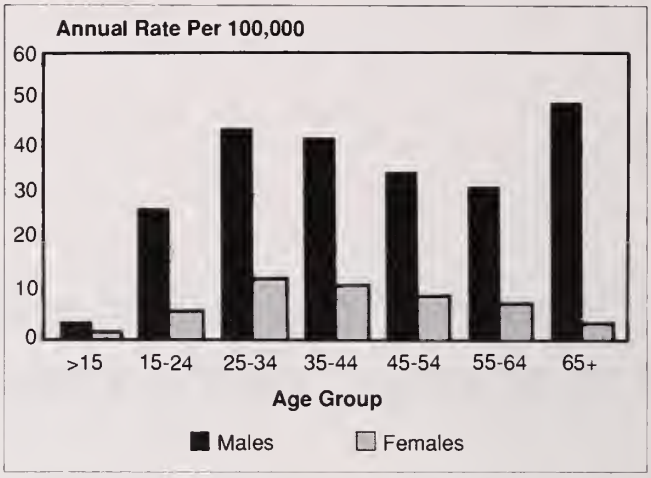
Firearm-Related Mortality. Between 1985 and 1989, 2,639 Oklahoma residents died from a gunshot wound (average 528 firearm deaths per year). Fire-

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arms accounted for 2% of all deaths (147,887) and 24% of all injury deaths (10,916) in Oklahoma during this time period. The firearm-related mortality rate in Oklahoma was 20% higher than the U.S. rate (17.4 vs. 14.5, respectively). Sixty-two percent (1,640) of the firearm deaths were reported as suicide, 30% (794) as homicide, and 4% (113) as unintentional; 1% (37) were due to legal interventions and intent was undetermined in 2% (55). Firearm-related deaths were the second leading cause of all injury deaths, behind traffic deaths (average 680 traffic deaths per year, including motor vehicles, pedestrians, bicycles, and motorcycles). Among black persons, firearms were the leading cause of injury death; 72% of firearm deaths among blacks resulted from homicide (Table 1). Among whites, over two-thirds (68%) of the firearm deaths were suicides. Native Americans had a slightly higher proportion of homicides than suicides (48% and 41%, respectively).

The rate of firearm deaths among males was 4.5 times higher than among females (29.1 and 6.4, respectively) (Fig. 1). Overall, combined male and female rates were highest among 25- to 34-year-olds, followed by 35- to 44-year-olds. Rates were highest among males 65 years and older. The female rate peaked among 25- to 34-year-olds. During the five-year period, firearm-related deaths accounted for 66,597 years of potential life lost before age 65, accounting for 24% of the total 272,467 years of potential life lost due to all causes of injury. The rate among blacks was higher than the rates among whites and Native Americans (25.8, 17.3, and 13.8, respectively). In fact, firearm- related deaths were the overall leading cause of death from all causes for blacks 15 to 29 years of age. Black males had the highest rate of unintentional gunshot fatalities and homicides; suicides were highest among white males (Fig. 2).

Residents of eastern Oklahoma had the highest firearm-related mortality rates in the state (Fig. 3). Among counties with more than 30 firearm-related fatalities during the five-year period, McCurtain County had the highest rate (28.2, 51 deaths). Oklahoma's two largest metropolitan areas, Oklahoma City and Tulsa, had comparable rates (19.7 and 18.0, respectively). The total number of firearm deaths was lowest in February and highest in August; homicides peaked in August and December, while suicides were fairly evenly distributed. The number of deaths due to firearms declined slightly among all categories of intention during the five-year period (Table 2).



Pam Archer

Figure 1. Firearm Mortality Rates by Age Group and Sex, Oklahoma, 1985–1989.

Firearm-Related Suicide. A total of 2,338 suicide deaths occurred in Oklahoma between 1985 and 1989; 1,640 (70%) of these were from gunshot wounds (average 328 firearm-related suicides per year). The Oklahoma rate of firearm-related suicides was 35% higher than the U.S. rate (10.8 and 8.0, respectively). Persons 65 years of age and older had the highest rate (19.4); rates were lowest among persons less than 15 years of age; however, the Oklahoma rate was twice as high as the U.S. rate for this age group (0.6 and 0.3, respectively).

Males were five times more likely than females to commit suicide with a firearm (18.4 and 3.6, respectively). Whites were more than twice as likely to commit a firearm-related suicide as Native Americans and blacks (11.8, 5.7, and 5.3, respectively); white males had the highest rate of firearm-related mortality (20.1). White males age 65 and

Table 1. Intention of Firearm Deaths by Race, Oklahoma, 1985-1989

Intention	Race			
	White # (%)	Black # (%)	Native American # (%)	Other # (%)
Suicide	1535 (68%)	54 (20%)	48 (41%)	3 (33%)
Homicide	541 (24%)	191 (72%)	56 (48%)	6 (67%)
Unintentional	97 (4%)	9 (3%)	7 (6%)	0 (0%)
Legal intervention	26 (1%)	8 (3%)	3 (3%)	0 (0%)
Unknown	50 (2%)	2 (1%)	3 (3%)	0 (0%)
Total	2249 (100%*)	264 (100%*)	117 (100%*)	9 (100%)

*Totals do not add up to 100% due to rounding.

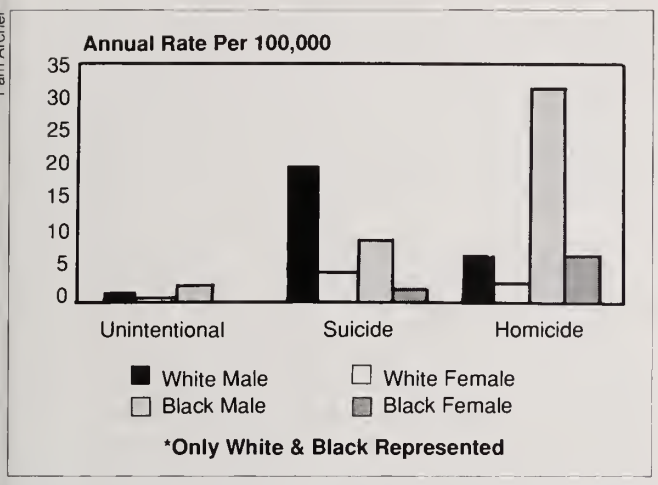


Figure 2. Firearm Mortality Rates by Race*, Sex, and Intention, Oklahoma, 1985–1989.

older were substantially more likely to commit suicide with a firearm (48.4) than white males at any other age.

The number of firearm-related suicides declined slightly over the five-year period; the decline was greatest among white males 15 to 24 years of age (33%). The number of firearm-related suicides among white males increased 22% among 35- to 44-year-olds and 8% among persons 65 years and older.

Firearm-Related Homicide. Between 1985 and 1989, a total of 1,343 homicides were committed in Oklahoma (average 268 deaths per year); 794 were committed with firearms (59% of all homicides). The overall firearm-related homicide rate in Oklahoma was slightly lower than the U.S. rate (5.2 and 5.6, respectively). Rates were lowest among persons less than 15 years of age and peaked among 25- to 34-year-olds, falling sharply after 44 years of age.

Males were 3.5 times more likely to die from firearm-related homicides than females (8.3 and 2.4, respectively). Blacks were 4.5 times more likely than whites and 2.8 times more likely than Native Americans to die as a result of firearm-related homicide (18.7, 4.2, and 6.6, respectively). Among black males, firearm-related homicide was the leading cause of injury death, accounting for almost one-fourth (23%) of injury deaths. It was the fourth leading cause of death overall in this high risk group. The rate was highest among black males 25 to 34 years of age (87.2). Although the number of homicide deaths among white males 25 to 44 years of age declined steadily during the five-year period (62 deaths in 1985; 29 deaths in 1989), the number of homicide deaths among black males 25 to 44 years of age remained relatively stable over the five-year period. The number of firearm-related homicide deaths during the five years fluctuated between a high of 180 (1986) and a low of 129 (1988).

Unintentional Firearm-Related Mortality. Between 1985 and 1989, 113 unintentional firearm deaths occurred in Oklahoma (average 23 deaths per year). The Oklahoma rate was slightly higher than

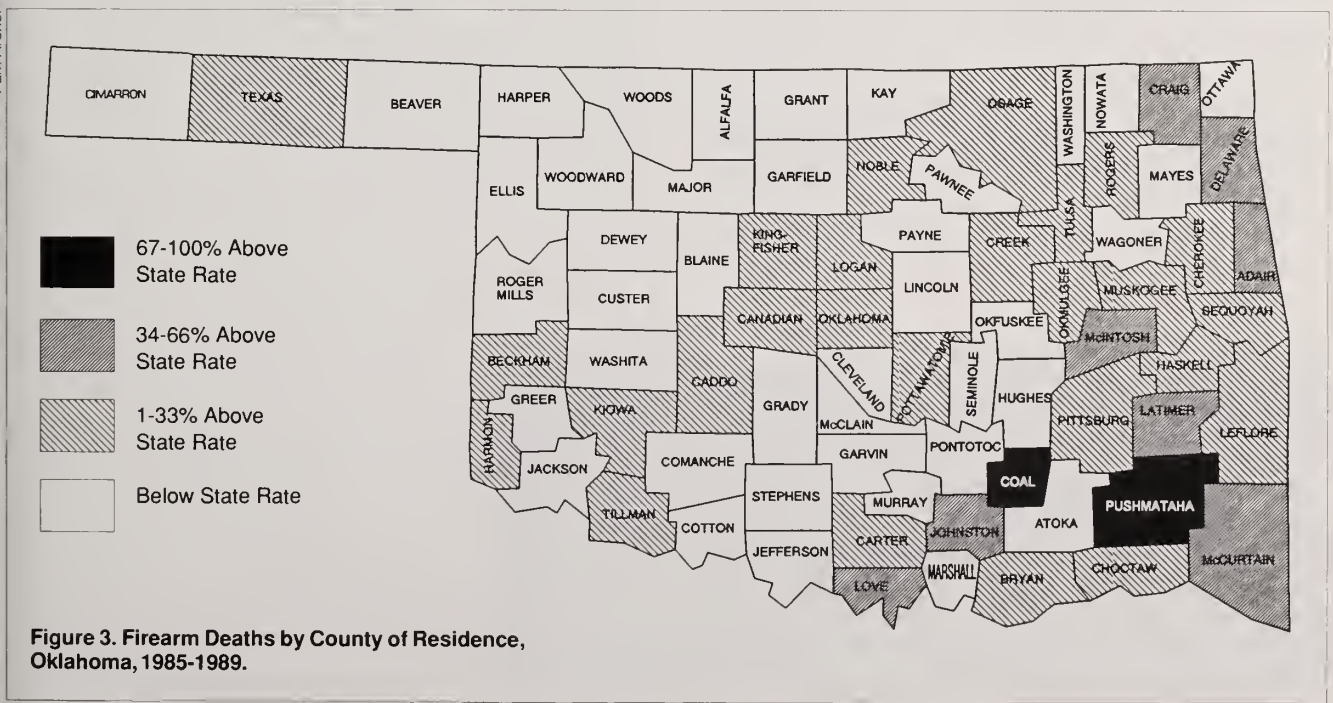


Figure 3. Firearm Deaths by County of Residence, Oklahoma, 1985-1989.

the U.S. rate (0.8 and 0.6, respectively). Unintentional firearm deaths accounted for 2% of all unintentional injury deaths (6,981 deaths). The unintentional firearm mortality rate was highest among persons less than 15 years of age, followed by 15- to 24-year-olds; this pattern differs from that of the U.S. and of states in the south central region of the U.S., where rates are nearly twice as high for 15- to 24-year-olds as compared to children under 15 years of age. In Oklahoma, 60% of all unintentional firearm-related deaths occurred among persons younger than 25 years of age. Males were 6.5 times more likely to suffer an unintentional firearm death than females (1.3 and 0.2, respectively). The rates among whites, blacks, and Native Americans were similar (0.8, 0.9, and 0.8, respectively). Overall, there was a slight decline in the number of unintentional firearm deaths over the five-year period.

Discussion

In Oklahoma, one to two persons are killed by a gun every day. Firearms are the eighth leading cause of all deaths and the second leading cause of injury death; firearms are the leading killer of blacks 15 to 29 years of age and the leading cause of injury death among all blacks. More than half of all Oklahoma suicides and homicides are a result of gunshot wounds. Additionally, it has been estimated that for each firearm death, five nonfatal gunshot injuries may occur.[10]

The Oklahoma Behavioral Risk Factor Surveillance System found that 50% of Oklahoma households surveyed indicated they owned one or more functional firearms; about 45% of Oklahoma households with guns own handguns. Although self-protection is a primary reason given for firearm ownership, research conducted in King County, Washington, revealed that for each firearm incident of self-protection in the home, 1.3 unintentional deaths, 4.6 homicides, and 37 suicides occurred.[11] Firearms in the home were 12 times more likely to kill a family member or an acquaintance than a stranger.

The costs associated with firearm injuries are considerable. A study in Oklahoma found nonfatal firearm injuries to the head resulted in a severe brain injury 91% of the time and had an average acute hospitalization charge of $16,000.[12] A study conducted in San Francisco found public sources paid 85.6% of hospitalization costs for firearm injuries; private sources paid only 14.4%.[13] Additionally, it has been estimated that persons suffering a severe brain injury have estimated lifetime health care costs of $4.1 million.[14]

Availability of firearms to juveniles who may carry weapons to school has recently become an issue. There have been an increased number of newspaper reports of students with firearms at school, including elementary schools. In the spring of 1992, one student was shot at an Oklahoma high school and subsequently died. Some schools have had success combating firearms in schools through the use of metal detectors and by maintaining a closed campus policy. Additionally, in May 1992, a law was effected in Oklahoma prohibiting the possession of weapons on public or private school property or on school buses. Persons convicted of violating this law are guilty of a felony punishable by a fine of up to $5000 and imprisonment of not more than one year.

The importance of self-inflicted injury by guns cannot be ignored. Suicides attempted by firearms result in death 92% of the time.[13] It has been shown that adolescents who commit suicide are significantly more likely to have had a gun accessible in their homes compared to suicide attempters and never-suicidal controls.[9] Several researchers have suggested that many suicides among young persons could be prevented if firearms were removed from the home, especially in households with high-risk persons.[15-17]

The high social and economic costs of firearm-related deaths and injuries make them a major public health problem. The Year 2000 Objectives for the nation include goals to reduce homicide, suicide, weapon-related deaths, the number of youth who carry weapons, inappropriate storage of weapons, and improvement in the design of handguns in order to protect children.[18] Recommendations outlined by the position paper "Prevention of Violence and Injuries Due to Violence" encompass encouraging voluntary removal of handguns from households and secure storage of firearms that remain in the home; developing and evaluating educational programs; developing less le-

Table 2. Firearm Deaths by Year & Intention, Oklahoma, 1985-1989

Intention	Year of Death					
	1985	1986	1987	1988	1989	Total
Suicide	339	347	336	314	304	1640
Homicide	168	180	164	129	153	794
Unintentional	24	20	24	27	18	113
Legal intervention	10	10	7	3	7	37
Undetermined	19	15	9	9	3	55
All firearm deaths	560	572	540	482	485	2639

thal means of security; promoting standards to minimize the risk of firearm injury (trigger arresters, loaded chamber indicators, etc.); intensifying legislative/regulatory efforts; establishing a handgun registry for criminal investigation; and instituting a national waiting period for all firearm purchases with a mandatory criminal background check.[19]

Though many Oklahoma public health, law enforcement, mental health, and school officials consider firearm injuries (especially intentional injuries) overwhelming and non-preventable, many, if not most, firearm-related deaths and injuries (whether intentional or unintentional) are predictable and potentially preventable. A collaborative effort between criminal justice, public and mental health, education, and medical practitioners could have a major influence on preventing these disabling injuries and deaths.

Despite the fact that state law requires physicians to report apparent criminally injurious conduct to county law enforcement agencies, detailed statewide data regarding the circumstances of events resulting in the injury (especially nonfatal injury) including perpetrator, health/mental health data, and contributing factors are not readily available in Oklahoma. Data regarding circumstances resulting in nonfatal injury may be very different from circumstances resulting in fatal injuries and need to be systematically collected. Collection of hospital data regarding firearm injuries requires hospitals to provide International Classification of Diseases (ICD-9) E-coding (external cause of injury) as a part of the hospital record. This could be accomplished by making E-coding a mandatory part of the Oklahoma Health Care Information System Act to be implemented in 1995. This detailed data collection is imperative in order for specific, targeted prevention programs to be designed. The magnitude of this problem makes it a major health problem deserving attention from Oklahoma health care providers and public health officials.

Acknowledgment

We thank Nancy Kinman for detailed preparation of the text and illustrations.

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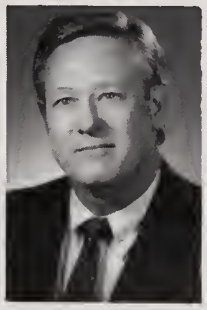
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News

Dr. G. Lance Miller assumes OSMA presidency in Tulsa this month

Tulsa physician G. Lance Miller, MD, assumes the presidency of the Oklahoma State Medical Association this month. He will be installed during a gala banquet on Saturday, April 24, at the Adam's Mark Hotel, site of this year's OSMA Annual Meeting. Dr. Miller becomes the association's 88th president, succeeding James D. Funnell, MD, Oklahoma City obstetrician-gynecologist.



Dr. Miller

A native of Washington, D.C., Dr. Miller completed his pre-medical education at Northeastern State College in Tahlequah and earned his medical degree at the University of Oklahoma College of Medicine in 1964. After completing his internship and a year of residency training at St. John's Hospital in Tulsa, Dr. Miller moved to Little Rock, Ark., for two more years of postgraduate work at the University of Arkansas University Hospital. He stayed there for a third year to complete a fellowship in hematology and oncology. During that time he was an instructor in the Department of Medicine.

Dr. Miller established his private practice in Tulsa in July 1969. In 1974 he was appointed director of medical oncology at St. John's Medical Center and became a clinical assistant professor at the University of Oklahoma, Tulsa Medical College, in 1976. Three years later, in 1979, he was named vice president of staff at St. John's and, a year later, director of the Medical Oncology Clinic at Muskogee Hospital.

During the next ten years, Dr. Miller became president of staff at St. John's, a clinical associate professor at OUTMC, and in 1991 was elected president of the Tulsa County Medical Society.

His professional affiliations include the American Society of Clinical Oncology, the American Board of Internal Medicine, and the American Board of Internal Medicine–Medical Oncology.

Dr. Miller and his wife, Judith Ann, have three children.

Medical staff bylaws subject of January meeting in Oklahoma City

On January 30, 1993, the Oklahoma State Medical Association–Hospital Medical Staff Section (OSMA-HMSS), in co-sponsorship with the Physicians Liability Insurance Company of Oklahoma (PLICO), presented a conference on hospital medical staff bylaws. There were over a hundred physicians, hospital administrators, and medical staff services personnel attending. The program was approved by PLICO as meeting the every-three-years mandatory loss prevention seminar attendance requirement for PLICO-insured physicians.

A discussion of credentialing problems encountered by hospital medical staffs, with special emphasis on Oklahoma law and cases as well as the federal antitrust laws, was presented by attorneys George F. Short, JD, and Cynthia Sparling, JD, of Oklahoma City.

William B. Smith, JD, senior attorney, Health Law Division, Office of the General Counsel, American Medical Association, presented an in-depth discussion of the principles and policies surrounding the drafting and revision of medical staff bylaws. This presentation reviewed many of the difficult and conflicting issues such as fair hearing procedures, economic credentialing, and credentialing of limited license practitioners by the medical staff.

During the luncheon, OSMA General Counsel Ed

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OSMA trustees name award winners at their mid-winter meeting

Two award winners were named by the Oklahoma State Medical Association's Board of Trustees at its meeting in Oklahoma City on February 21. The awards will be presented at the Annual Meeting of the OSMA House of Delegates in Tulsa this month.

Dr. Joan K. Leavitt, longtime Oklahoma commissioner of health, will receive the Wyeth-Ayerst Physician Award for Community Service. Dr. Leavitt has announced her retirement, effective June 31. Receiving the Donald J. Blair Friend of Medicine Award will be Ms. Pat Maly of Enid.

In other action, the board approved the filing of an amicus curiae brief in the appeal of a recent Tulsa court decision regarding privileged information. In that case, *Fields vs. Shaw,* the judge ruled that patient information is not considered confidential. The decision is being appealed.

The board discussed the matter of Noble County physicians wanting to disassociate from the Kay-Noble County Medical Society and merge with the Payne County Medical Society. As part of the procedure, the board must ask the Payne County group if they will accept the Noble County physicians, and the board voted to do so.

The board approved Life Membership applications from the following OSMA physicians: Drs. Leonard R. Diehl, Warren Felton II, and Fanning Miles, Oklahoma City; Drs. Fulton W. Fite and Frank Mahan, Muskogee; Dr. Alice Gambill, Stillwater; Dr. Ralph Heine, Elk City; Dr. Jack Honaker, Frederick; Dr. Robert Jabour, Tulsa; Dr. Clifford Lorentzen, Ardmore; Dr. Ray V. McIntyre, Kingfisher; and Dr. John Rollins, Washington.

With regard to health care reform plans now being formulated at both the state and national level, no specific action was endorsed by the board.

Medical staff bylaws *(continued)*

Kelsay presented a provocative discussion, "The Future of the Medical Staff."

The National Practitioner Data Bank was reviewed regarding the problems associated with querying and reporting to the data bank. The issues of confidentiality and accuracy of the data bank were reviewed, including possible suggestions to medical staff credentialing committees and hospital governing boards concerning protection of the hospital and medical staff from monetary and other penalties by the data bank.

Attendance at this conference on medical staff bylaws reflected a keen interest in this subject. A detailed handbook of the subjects discussed was presented to those attending and should be a valuable reference in reviewing and revising hospital medical staff bylaws.

Your OSMA-HMSS reminds all physicians that whenever drafting and revising or amending medical staff bylaws, you should seek legal counsel from an attorney knowledgeable in this matter and retained by the medical staff—*not* by the hospital administration.

Questions and/or comments are welcome and encouraged regarding the issue of medical staff bylaws or other information and news items published in the OSMA JOURNAL by your OSMA-HMSS.

—William O. Coleman, MD
Chairman, OSMA-HMSS
—Robert W. Baker III
Associate Director, OSMA

OSMA Leadership Conference holds an attentive audience from 9 to 5

The OSMA sponsored a Leadership Conference February 19 in Oklahoma City. The program was presented by Glenn Tecker, PhD, international consultant. Throughout the day, the audience listened attentively as Tecker led them through discussions and exercises in association management, organization, leadership, strategic thinking, goal-setting, and analysis of association strengths and weaknesses.





Top: Drs. Mukesh Parekh, Joe Crosthwait (c), Mike Schwartz, and the rest of the audience give Tecker their full attention.

Right: Dr. Philip Mosca concentrates on an exercise.

Health Department

Rural health outreach program accepting grant applications

Oklahoma's rural physicians who are working with communities to develop innovative ways to deliver health care services should note the availability of federal monies from the Rural Health Outreach Grant Program.

The federal Office of Rural Health Policy has officially opened competition for its Rural Health Outreach Grants to fund projects for underserved populations. Applicants will have a chance at $3 million in new grants under this year's competition, which will lead to approximately 15 grant awards. Awards are made for up to three years. The deadline for applications is May 1, 1993.

The program supports projects that will deliver services to rural residents who may be without access to medical services due to geography and/or poverty. Oklahoma has 31 counties either fully or partially designated as Health Professional Shortage Areas, and 59 counties are either fully or partially designated as Medically Underserved Areas. A recent report by the American Public Health Association ranks Oklahoma 50th in the number of physicians per capita. Seventy-seven percent of the allopathic and osteopathic physicians in the state practice in urban areas. Physician assistants and nurse practitioners follow the same pattern, with 64 percent of Oklahoma's mid-level practitioners serving in urban areas.

Applicants are not bound by a particular approach to solve their health care delivery needs, so they can be creative in tailoring local solutions to local problems. Among the few design requirements are that grantees must be in a rural area or rural section of a metropolitan statistical area, be from non-profit organizations, and applicants must capitalize on existing resources by forming a consortium.

The competition is expected to be very keen, so grant applicants must clearly document that they have a thorough understanding of the health care needs in their community. In addition, consortium members must have a substantial role in solving the identified health care needs. Innovative approaches in meeting often complex rural health care dilemmas will boost the applicant's competitiveness.

Individuals interested in applying for a Rural Health Outreach Grant should contact the Oklahoma Office of Rural Health, Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1299, or phone (405) 271-8427 for additional information.

85 Years Ago

Politicians moving on reform bill as physician opinion discounted

...We have no completed medical legislation up to this date, so far as I am aware, and the legislation that is now undergoing the process of incubation is of such character as to be wholly inadequate to meet the urgency of the situation and instead of improving our condition will probably make it worse. Why is this? For two reasons: First: For no other than sordid political purposes. Second: We have division within our own ranks. We are un-united as touching the needs of our profession and the people of the commonwealth.

Let us descend from the pedestal of our professional importance, put on the spectacles of the laity, and endeavor to see ourselves as they see us, and perhaps we will be wiser and know better how to proceed and to succeed. Individually, we may be regarded by our friends who know us best, as men of influence, honor and integrity, socially and morally above reproach and financially and otherwise responsible; so much so that we are entrusted with the care of all they hold dear in this world.... Collectively, they regard us as a profession the members of which are on a par; they do not, and cannot, for lack of proper knowledge, make the proper distinction. They behold us as a body of professional men bent on each other's destruction and speak of us with ridicule because we are divided in our opinions. They see no good reason for a division of opinion as touching any one thing if it is a proven truth, hence they are led to doubt our sincerity and attach little importance to the reforms we advocate.... The legislator is usually a layman, and views us through layman eyes;... and since he sees that we do not know what we want ourselves, as is evidenced by our strifes, divisions and dissensions, he is more easily swayed by the persuasions of the designing politician who is anxious to strengthen his lines and enhance his chance of future success by catering to the demands of those who have

come into existence through the creation of an unmerited prejudice. What may we do to overcome this condition of affairs?...

...I am convinced that the time has come when we must enter into the political arena as professional men;... So long as legislative matters are left entirely to the influences of designing politicians, just so long will we have compromise laws; and just so long as we permit internal dissensions and corruptions to exist, just so long will we have a repetition of our recent experience. The average politician is insured against threats and appeals, and is wholly insensible to criticism.... The only thing in this world that he fears is unity of purpose and decisive action on the part of his opposition. In this latter lies the hope of our success. Let us see if we may muster enough to disturb him.... When we awake to the duty, as well as the opportunity confronting us, we will get what we know is needed to best serve the greatest number, both in the profession and out...

—Floyd E. Waterfield, MD
Chairman, Section on Practice of Medicine
"Address of Dr. Floyd E. Waterfield"
J Okla State Med Assn, *July 1908*

Note: *In early 1908, the OSMA Committee on Medical Legislation and Public Policy was struggling to reach some agreement with the Oklahoma Legislature on provisions of a new Medical Practice Act. Dissatisfied with the legislation ultimately enacted, the committee would cite two reasons for its failure: lack of harmony within the OSMA and opposition of the "so-called irregular schools of medicine on the outside" (homeopaths, eclectics, physio-medicals, and osteopaths, all practicing legally under the state's new constitution).*

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Letters

■ Big Brother alive and well at OBN?

To the Editor: RE: Who is treating our patients? I have recently heard from several patients that, because of new state legislation, Oklahoma physicians are no longer able to prescribe more than a single medication from any "drug category." This was news to me, and my secretary checked with our neighbors who likewise had heard nothing of this. The liability department of PLICO also knew nothing of this legislation. The liability department of the OSMA was similarly at a loss. The DEA was also in the dark. At the OBN, my secretary spoke to an agent who had also heard of no legislation, but considered that prescribing two drugs from the same category, such as amitriptyline and imipramine, would look very peculiar and might provoke a question from the OBN. He strongly cautioned against such prescribing.

Has the OBN embarked on a campaign to mold physicians' prescribing practices more to its liking? This near-Orwellian situation needs an airing.

I am therefore inviting those with relevant information or opinions to share the same in these columns.

—Michael E. Serjeant, MD
Oklahoma City

Can anyone out there explain this blemish? It may be one more example of the governmental agent who has never finished medical school, but who can't resist trying to practice medicine anyway. —Ed.

In Memoriam

1992	
Claude Marion Bloss, Jr., MD	February 24
Oliver James Hagg, MD	March 31
Francis Patrick Cawley, MD	April 17
Don Horatio O'Donoghue, MD	April 20
Billie Gene Henley, MD	April 24
Arlo Kenneth Cox, MD	April 27
Charles Victor Williams II, MD	May 1
Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28
1993	
Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd bell, MD	January 23
William Ray Turnbow, MD	February 28

Annual Meeting events planned

As this issue of the Journal goes to press, the following program is the latest information for activities scheduled in Tulsa, site of this month's 87th Annual Meeting of the OSMA House of Delegates. The meeting, at the Adams Mark Hotel, begins Thursday, April 22, and continues through Sunday, April 25.

Thursday, April 22, 1993

Noon:	OSMA Executive Committee
1:30 PM:	OSMA Board of Trustees

Friday, April 23, 1993

7 AM:	OSMA Hospital Medical Staff Section Breakfast
7 AM:	OSMA Council on Rural Health Breakfast
7:30 AM:	Tulsa County Medical Society Caucus
8:30 AM:	OSMA House of Delegates Opening Session
10:30 AM:	OSMA Reference Committees
Noon:	OSMA/OSMAA Luncheon *Keynote Speaker: AMA Executive Vice-President James S. Todd, MD*
1:30 PM:	OU College of Medicine Scientific Program

1:30 PM: Oklahoma Surgical Association Scientific Program
1:30 PM: Health Care Reform Summit
Panel Members: AMA Executive Vice-President James S. Todd, MD; Senator David L. Boren; Oklahoma State Representative Angela Monson; Garth L. Splinter, MD; and practicing physicians
3:30 PM: Candidates Forum
6:30 PM: OU College of Medicine Alumni Association Reception and Dinner
Presentation of Physician of the Year and Amicus Medicinae Awards

Saturday, April 24, 1993

8 AM: OSMA Past Presidents' and County Presidents' Breakfast
8 AM: Oklahoma Urological Association Program
9 AM: Oklahoma Medical Political Action Committee (OMPAC) Annual Meeting
9 AM: Office Management Seminar
Presented by Harrison and Associates
9 AM: Estate Planning Program
Presentor to be announced
9 AM: International Medical Graduates Meeting
10 AM: Scientific Program
Sponsored by OSMA Women in Medicine
Topic: Teen Pregnancy—Postponing Sexual Involvement
Speaker: Marion Howard, PhD, Emory University, Atlanta
Noon: OSMA Luncheon
Hosted by OSMA Women in Medicine
Speaker: Marion Howard, PhD
Noon: Oklahoma Surgical Association Luncheon
1:30 PM: PLICO Loss Prevention Seminar
6 PM: OSMA/OSMAA Presidents' Reception
7 PM: OSMA/OSMAA Presidents' Inaugural Banquet *(Black tie optional)*
Speaker: Robert S. Eliot, MD, Director of Institute of Stress Medicine, Denver, and author of Stress: Is It Worth Dying For?

Sunday, April 25, 1993

8 AM: Tulsa County Medical Society Caucus
8 AM: OSMA Rural Caucus
9 AM: OSMA House of Delegates Closing Session
11 AM: PLICO Forum *(convenes immediately following OSMA House of Delegates)*

Deaths

William Ray Turnbow, MD
1908 - 1993

OSMA Life Member William R. Turnbow, MD, died February 28, 1993, in Tulsa. A 1936 graduate of the University of Oklahoma School of Medicine, Dr. Turnbow completed his postgraduate training in Tulsa and remained there to establish a general practice. During World War II he served for three and one-half years with the U.S. Army and held the rank of major when discharged. His overseas duty included working as an anesthetist at the 56th Evacuation Hospital in Anzio, Italy, during the allied assault there.

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Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

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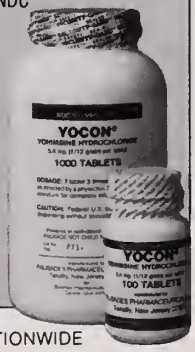
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

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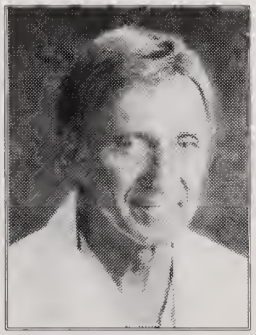
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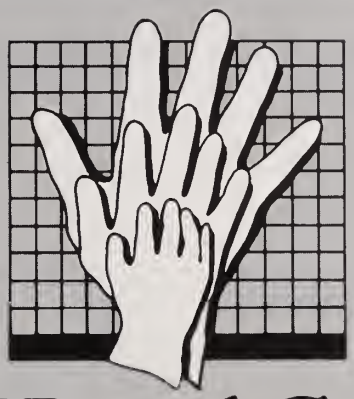
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Contributions

Articles submitted for publication become the sole property of the Journal and must not have been published elsewhere. The Editorial Board reserves the right to edit any material submitted. Manuscripts must be typewritten in a standard size and typeface suitable for scanning, double-spaced, and submitted in duplicate (original and one copy). Authors who can do so are encouraged to submit their manuscripts on computer disk as well; disk should be in ASCII/text-only format or DOS WordPerfect and clearly labeled with the manuscripts' title and author. The Journal does not assume responsibility for the statements or opinions of any contributor.

Style

All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style*. An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

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Illustrations other than the author's will not be accepted for publication unless accompanied by written permission from the original source. Illustrations should be labeled with the author's name and must be numbered in the order in which they are referred to in the article. The quality of all illustrations must be in keeping with the quality of the magazine.

Reprints

Authors will receive reprint order forms from the Transcript Press, PO Box 6440, Norman, OK 73070-6440, with their galleys. Other requests for reprints must be made to the Transcript Press within 30 days after publication.

OSMAA State Convention

This year the auxiliary's State Convention is April 22–24 at the Adams Mark Hotel, Tulsa. Our convention officially begins with the pre-convention joint board meeeting and luncheon, 11:30 AM, Thursday.

Thursday evening plans have been made for auxiliary members, spouses, and guests to have dinner and then tour the Designer Showcase House, which is reserved for the auxiliary that evening. This year's house is the former home of the Murl P. Springer, MD, family. Dr. Springer was the founder of Springer Clinic in Tulsa. The mansion is a 12,000 square foot, three floor, Victorian-Tudor and was built in the early 1900s. It is located in the Tulsa Country Club neighborhood. One of the outstanding features of the house is its circular staircase. The house was sold to the Masons in the fifties and a bingo parlor, which seats approximately 100 people and also has a bandstand, was added to the back of the house. Thirty-eight areas will be decorated by local designers.

This event will also serve as a reception for OSMAA President Judy Critchfield, OSMAA President-Elect Karen Mask, AMAA officer Lee Van Giesen from California, SMAA President Ebba Dunn from Alabama, and visiting officers from adjacent states.

Friday morning will begin with breakfast honoring our past state presidents. There will also be a breakfast for county presidents and presidents-elect, at which time they can share and discuss common concerns. At 9 AM the auxiliary will convene to discuss a name change (Auxiliary to Alliance). The House of Delegates will follow with the installation of officers for 1993-94. We will then join the OSMA for lunch and to hear guest speaker James Todd, MD, executive vice-president of the AMA. Early that afternoon there will be an Antique Auction benefiting AMA-ERF, with proceeds to benefit the medical school of your choice. All OSMAA members, their physician spouses, and guests are invited to bid on the antiques. Friday evening the University of Oklahoma College of Medicine Alumni Association will host a reception and dinner.

Saturday morning the auxiliary adjourns its convention after a post-convention board meeting and breakfast. That evening the OSMA and OSMAA Presidents' Reception and Banquet will be held at the hotel. Speaker for the evening will be Robert S. Eliot, MD, present director of the Institute of Stress Medicine in Denver and author of *Stress: Is It Worth Dying For?*

—Nora H. White
State Convention Chair, 1992-93

THE LAST WORD

■ **The Oklahoma Medical Political Action Com–** mittee (OMPAC) will hold its annual meeting at 9 AM Saturday, April, 1993, at the Adam's Mark Hotel in Tulsa. The purpose of the OMPAC meeting is to elect a new Board of Directors. A minimum of five physicians will be elected from each of the state's six Congressional districts. OMPAC members are encouraged to attend the meeting. Each member may nominate candidates for the board and/or run for a position on the board.

■ **Joan K. Leavitt, MD, Oklahoma Commission-** er of Health, has announced her plans to retire June 30, 1993. Her successor, Tom Peace, PhD, deputy commissioner since 1981, assumed the commissioner's duties February 1. Dr. Leavitt will stay on as senior medical advisor until the end of June.

■ **Physician training in child abuse and neglect** examination will be conducted May 21–22 at the Hilton Inn Northwest in Oklahoma City. Sessions will be held from 3:30 PM to 8 PM on Friday and 8 AM to 3:30 PM on Saturday. Lodging, snacks, and registration are provided to participants. CME credits will be available. Similar sessions were scheduled March 12–13 in Tulsa. For enrollment information, call the office of Chief Child Abuse Examiner Robert W. Block, MD, (918) 838-4725.

■ **Telephone numbers worth posting in a promi-** nent place: Oklahoma Poison Control Center: (405) 271-5454 in the Oklahoma City metro area or 1-800-522-4611 statewide. The center is part of Children's Hospital of Oklahoma, with participation from the University of Oklahoma College of Pharmacy.

■ **The University of Oklahoma Health Sciences** Center (OUHSC) in Oklahoma City has been selected as the recipient of the 1992 Oklahoma Red Ribbon Campaign Non-Profit Corporation of the Year Award. The university was honored for an in-depth, week-long alcohol and drug awareness program sponsored by its Employee Assistance Program.

■ **Physicians are being asked to advise their** legislators of all smoking-related deaths in Oklahoma and, in doing so, to support anti-tobacco legislation. To aid in this awareness campaign, the OSMA is providing printed postcards, pre-addressed to the Oklahoma legislature, at no charge. The cards state that one of the legislator's constituents has died of a smoking-related illness, and provide a place to check the type of illness involved. The message closes with a request to support anti-tobacco legislation. To order cards, write to the OSMA, 601 Northwest Expressway, Oklahoma City, OK 73118, and indicate the number of cards needed.

■ **As of January 1, 1993, the U.S. Post Office is** no longer delivering the old Reportable Disease Cards (3" × 5", yellow for laboratories and blue for practitioners) to the Oklahoma State Department of Health. All physicians, nurses, institutions, infection control practitioners, and laboratories should now be using the revised Reportable Disease Card (Rev. 2/92, blue, 6" × 8", sent with pre-addressed envelopes). Those needing a supply of the new cards should call the OSDH Communicable Diseases Division, (405) 271-4060.

■ **Fred G. Silva, MD, Lloyd E. Rader professor** and chairman of the OUHSC Department of Pathology, has been selected to chair the Education Committee of the United States and Canadian Academy of Pathology (USCAP). His three-year appointment began April 1. The committee is charged with developing, coordinating, and operating the major annual meeting of the U.S./Canadian Division of the International Academy of Pathology, as well as directing all educational aspects of the USCAP.

■ **Renewal notices for Oklahoma state medical** licenses (1993–94) were mailed in March. The completed form and accompanying fees must be returned to the Board of Medical Licensure and Supervision by July 1, 1993, if the license is to be kept active. The board reminds physicians that the most common reason for failure to renew a license is not having notified the board of a change of address, causing the renewal notice to go astray. Physicians who have not yet received their notices should contact the board immediately at P.O. Box 18256, Oklahoma City, OK 73154-0256, or (405) 848-6841.

■ **Marie Bernard, MD, associate professor and** director of geriatrics in the OUHSC Department of Internal Medicine, has been named director of the Oklahoma Geriatric Education Center. The center, begun in 1989, is a federally funded facility designed to increase the availability and quality of health care for older Oklahomans by providing training for health and social service professionals.

Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991,14:146-151.

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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Prevastatin should be administered to women of childbearing age only when such petients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletel Muscle: Rhabdomyolysis with renel dysfunction secondery to myoglobinuria has been reported with prevastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporerily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; treume; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosponne. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomenc metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Petients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinc Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfann: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfann-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 6 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

No interaction studies with *aspirin*, antacids [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine*, *nicotinic acid*, or *probucol*, no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

Carcinogenesis Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS, **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitounnary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive. gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Leboretory Test Abnormelities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemtibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interections.**)

OVERDOSAGE

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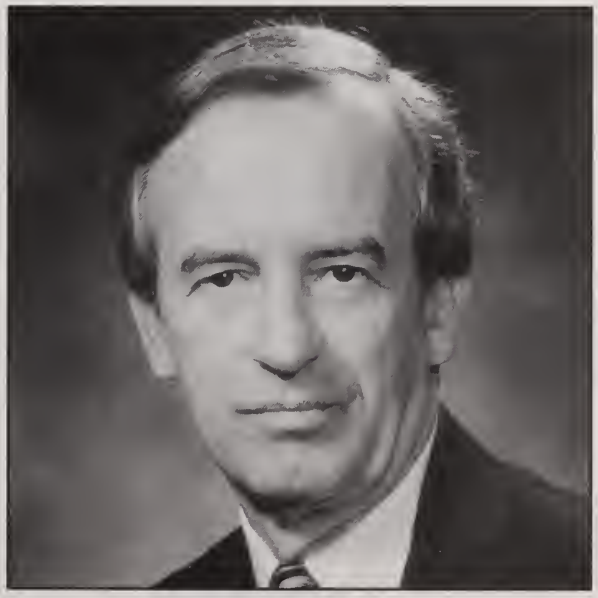
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JOURNAL

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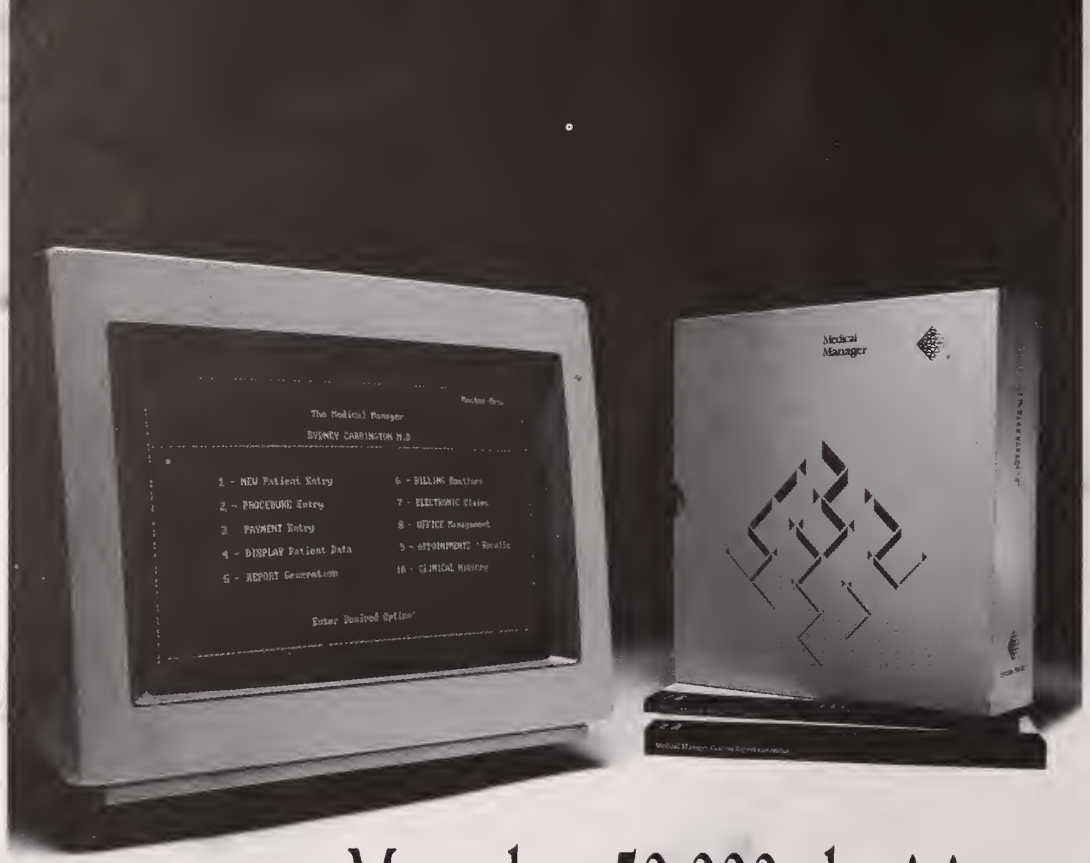
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ABOUT THE COVER

David Allen Brown's sculpture *Untitled* reaches skyward from downtown Tulsa. Photograph by Ray V. McIntyre, MD, Kingfisher. Art direction by Graphic Art Center, Oklahoma City.

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EDITORIAL

Ray V. McIntyre, MD

On Word Twisting

There are aggressive cliques engaged in altering America's social structure, and a favorite weapon is the use of emotion-laden words in our daily social discourse. These "loaded" or "hot" words evoke an emotion in the hearer in addition to the factual message. For example, the word *mother* carries with it an aura of warmth and security in addition to the information on parenthood. The use of the word *worm* suggests low and loathsome, even when describing a butterfly precursor.

The omnipresence of this loaded word phenomenon was recently emphasized when the chairman of the OSMA Board of Trustees, Dr. Jay Gregory, advised that board to exhibit sensitivity to women's issues by carefully avoiding use of the words *girls* and *ladies.* Currently the preference is *females* or *women.*

This striking exposition of word usage reminded me of the state of affairs during my own boyhood in rural Oklahoma. In that olden time my mother's colleagues were invariably "ladies." *Young ladies* was an acceptable age-related variant. The feminine pre-pubescent were always "girls." In that era the word *women* was applied only in a vulgar or derogatory connotation, as in "fallen women" or "women of the street." The only "females" in the township during my boyhood were the milk cows and the mothers of the hunting dogs.

However, word usage evolves, and the pressure for social and political change is constant in our society. The "spin" on our emotion-laden words affects our politics and may alter human relationships. Since my boyhood, the implications of many words have changed. Some of the racial epithets of that time have now become polite labels, and some polite appellations of that time are now considered racial slurs.

In addition to re-definitions, some words undergo a progressive devaluation under pressure for political change. About two hundred years ago our ancestors fought a nearly hopeless war in order to establish the human "right to life, liberty, and the pursuit of happiness." Those prophetic patriots pledged their lives, their liberty, and their treasure to that quixotic quest and, miraculously, succeeded in establishing that "right" in the United States Constitution.

Over the succeeding years, the noble concept of natural right has been devalued and diluted. Political and social movements have advanced the "right" to own property and the "right" to vote. There is now a major political effort underway to establish a "right" to health care and a "right" to paid holidays. A recent TV advertisement boldly asserted that "everyone has a 'right' to glasses that fit." This commercial trivialization of a concept for which the nation's founders gave their lives denotes a significant devaluation of the word *right.* If we have a "right" to everything we want, we will find that we have a right to nothing of intrinsic importance.

Our thinking patterns are altered by word usage, and sometimes cliques manage the evolution of that word usage.

Ray V. McIntyre, M.D.

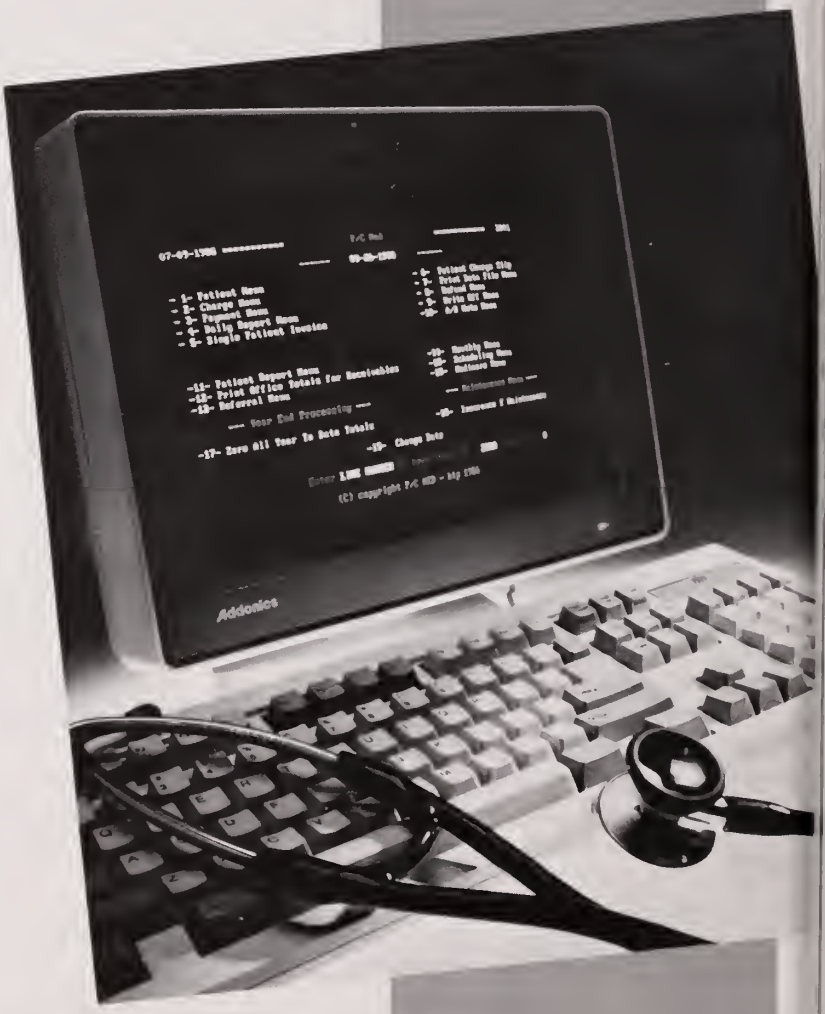
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PRESIDENT'S PAGE

G. Lance Miller, MD

Getting Our Political Act Together



Of all the important tasks this association has undertaken, political activities have always been at the very top of the list. For many years now I have been intimately involved in these activities at both the county and the state level, and I can assure you that our political influence and lobbying efforts have been successful.

The vast majority of our members have no concept of the many vectors continually attempting to influence the politics of medical care, usually in ways that would be detrimental to the quality of care for Oklahomans and to the welfare of Oklahoma physicians. For the most part, physicians also are unaware of the many political battles we have won, and thus the many unpleasant, possibly disastrous, consequences we have averted for them.

Have we won all the skirmishes and battles? Of course not. We can never win them all. But we must continue to improve our efforts.

Most of you are at least dimly aware of who our political "enemies" are, but in these troubled times, even some of our traditional allies have turned against us. One example, as reported in the October issue of this journal: the top advisory board for hospitals throughout the country has issued a doctrine for hospitals that makes "gaining control of physicians" a top priority.

It is absolutely clear that organized medicine must take aggressive measures to enhance its ability to influence health care legislation. Never before has it been so imperative for physicians to abandon their antiquated views of politics and take an active part in the process.

This association has been blessed with intelligent and proactive lobbyists who have done yeoman's service for us all, as well as a handful of leaders who have spent many hours on our behalf. It is painfully obvious, however, that the efforts of these key individuals are not nearly enough. To be as successful as we must be, they need the active backing of every member.

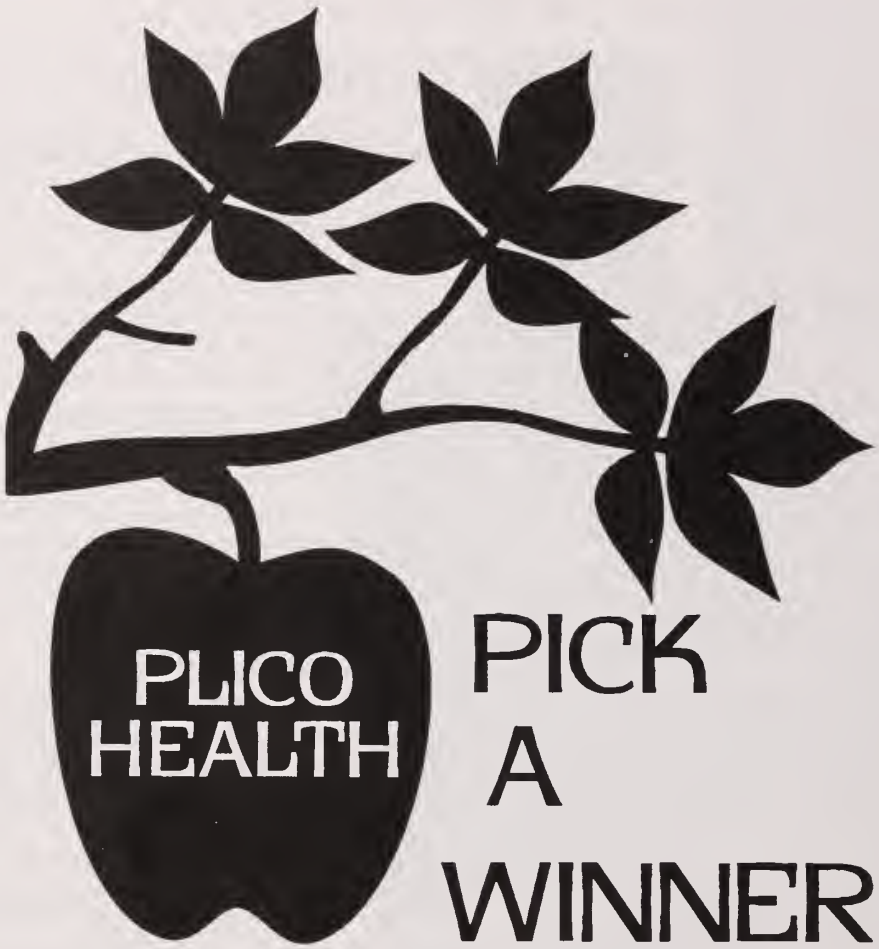
To this end, your leadership has embraced the formation of a new political action program that we will call IMPACT. During the coming year, I will attempt to meet with all the county societies to explain this new program and enlist the active support of all OSMA members.

Throughout the state, physicians are voicing concerns that the association do more to protect them, and to those physicians I say: Your leaders can do only so much by themselves, but with a unified effort by all concerned, we can exert a tremendous influence on the forces aligned against sane and sensible medical care.

This is an opportunity for each physician in Oklahoma! An opportunity to stop just "taking it on the chin" and start taking positive action to control your destiny. Being involved in IMPACT will not require you to give countless hours of your time—there are many dedicated physicians in leadership roles who are willing to put in the time and effort for you.

The basic framework of this program will depend on "key contact" individuals throughout the state, so if you are interested in learning the political process and in taking an active role, please call me and sign up. Let's get our act together and get with it!

G Lance Miller, MD



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SCIENTIFIC

The Magnetic Resonance Appearance of Extraperitoneal Bowel Perforation: A Case Report

Philip L. Johnson, MD; Minh Nguyen, MD; Justine Dautenhahn, MD; John A. Owen, MD

The use of magnetic resonance imaging (MRI) for abdominal and gastrointestinal imaging has been quite limited, when compared to its utilization in other organ systems. We present an interesting case of extraperitoneal bowel perforation, which was diagnosed by magnetic resonance (MR). Extraperitoneal bowel perforation is frequently a confusing and difficult diagnosis to make. The multiplanar imaging capability and unique sensitivity of MR to fluid enabled a specific diagnosis to be made in this challenging case.

The use of magnetic resonance imaging for abdominal and gastrointestinal imaging has been quite limited, when compared to its use in other organ systems. We present an interesting case of a sixty-nine-year-old female with diverticulitis, abscess, and extraperitoneal perforation of the sigmoid colon, which was diagnosed by MRI. To our knowledge this is the first case reporting the MR appearance of extrapelvic bowel perforation.

Case Report

A sixty-nine-year-old white female with rheumatoid arthritis presented with the complaint of increasing bilateral hip pain for approximately two weeks. She had been taking prednisone, azulfidine, and methotrexate for several months for treatment of rheumatoid arthritis. One month earlier, she experienced vague lower abdominal pain associated with constipation. In addition, she had developed a low grade fever over the preceding month. She denied other gastrointestinal complaints. Her WBC count and hemoglobin were 12,200 and 11.4 g/dl, respectively, at her initial visit one month earlier. The source of her fever was not evident, and her personal physician concluded that her fever was due to an exacerbation of rheumatoid arthritis. She was treated with oral analgesics and her symptoms improved until the day before admission, at which time her hip pain had become incapacitating. Physical examination revealed only mild nonspecific tendernesss in the lower abdominal quadrants. Neither rebound tenderness nor abdominal distention was present, and the bowel sounds were normal. Her temperature was 100.6° F, the pulse rate was 129, and the blood pressure was 125/80 mm Hg. Plain radiographs of the hips revealed gas collections in the region of both hips, most prominent in the region of the of the right greater trochanter (Fig. 1). The patient was admitted to the hospital with a presumptive diagnosis of necrotizing fascitis.

MR scan of the hips was performed for further evaluation. Axial T2 weighted images (Fig. 2) demonstrated large air fluid levels in the region of the pyriformis muscle bilaterally, somewhat larger on the right. Coronal T2 weighted images (Fig. 3) revealed hyperintense tubular shaped fluid collections along the pyriformis muscles bilaterally. Axial T2 weighted images (Fig. 4) superior to the previous axial image at the level of the mid sacrum demonstrated an area of heterogenous increased signal intensity measuring approximately 7 cm × 4 cm contiguous with the sigmoid colon anteri-

Direct correspondence to Philip L. Johnson, MD, Baptist Medical Center, Department of Radiology, 3300 Northwest Expressway, Oklahoma City, OK 73112.



Figure 1. Radiograph of the right hip demonstrates a collection of gas within the soft tissues just lateral to the greater trochanter.



Figure 2. Axial TR:2000 TE:80 256×192/2.0 NEX demonstrate large air fluid levels in the region of the pyriformis muscles, slightly more prominent on the right. Increased signal intensity within the right gluteus muscles and subcutaneous fat is also noted.

or to the sacrum. In addition, there was diffuse increased signal intensity of the soft tissues in the region of the right hip seen best in Figures 2, 3, and 4, which most likely represents edema. Diverticulitis with perforation, abscess, and extraperitoneal spread of pus and bowel contents from the pelvis to the hip and thigh region was suspected, based on the MR findings. Gastrografin® enema (Fig. 5) was performed, revealing narrowing of the distal sigmoid colon and extravasation of contrast from the sigmoid colon along the course of the pyriformis muscle bilaterally.

The patient immediately underwent surgery for a Hartman's procedure and abscess drainage. At surgery, extraperitoneal sinus tracts were identified along the course of pyriformis muscles without evidence of intraperitoneal involvement. A boggy abscess was present anterior to the sacrum with associated marked induration and thickening of the sigmoid and rectosigmoid colon consistent with perforation. There was no evidence of muscle or fascia necrosis. The patient tolerated the procedure well and had an uneventful recovery. She was discharged from the hospital in good condition on the 25th postoperative day.

Discussion

The diagnosis of extraperitoneal bowel perforation is notoriously difficult and challenging for the clinician. These patients typically present with nonspecific complaints. Their pain may be poorly localized and vague, with low grade fever and mild gastrointestinal symptomatology. Frequently, the diagnosis is delayed, resulting in significant morbidity and mortality. Often it is the radiologist who first suggests the correct diagnosis. This case represents an excellent example of the diagnostic difficulty and confusion typical of these patients. However, it is unique because of the extensive pathologic changes attributed to the use of prednisone. Presumably, the prolonged use of steroids masked the imflammatory changes, and the patient's hip pain and low grade fever were erroneously attributed to rheumatoid arthritis. Thus, a normally very difficult diagnosis became even more confusing and misleading.

The various potential pathways of extrapelvic spread of disease were nicely described by Meyer and Goodman in 1975.[1] The extrapelvic spread of disease is related to the insertions and fascial planes of the iliopsoas, pyriformis, and obturator internus muscles as well as the course of the superior gluteal artery.[1] In this case the spread of bowel contents occurred along the course of the pyriformis muscle. The pyriformis muscle originates from the anterior surface of the sacrum, exits through the greater sciatic notch, and inserts at the greater trochanter. Consequently, the fascia of the

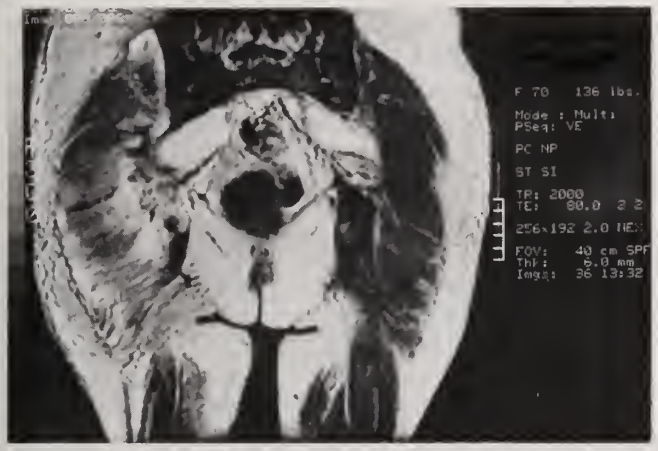


Figure 3. Coronal TR:2000 TE:80 256×192/2.0 NEX reveals hyperintense fluid collections along the pyriformis muscles bilaterally. Again increased signal intensity is apparent in the right gluteus muscle, which was felt to represent edema.

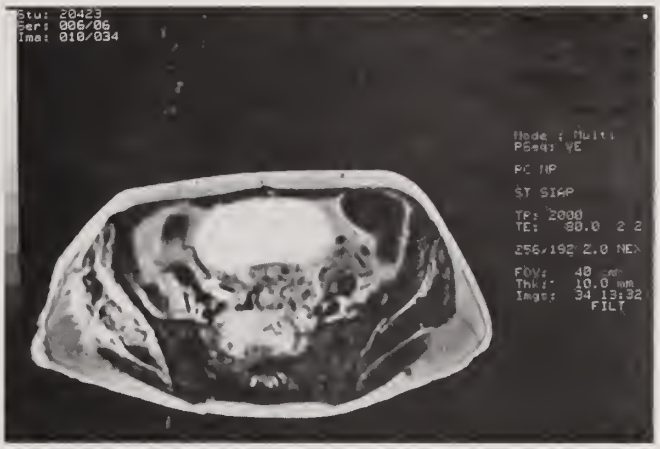


Figure 4. Axial TR:2000 TE:80 256×192/2.0 NEX image superior to the previous axial image at the level of the mid sacrum demonstrated an approximately 7 cm × 4 cm region of increased signal intensity in direct contiguity with the posterior sigmoid colon and anterior to the sacrum, which was felt to represent an abscess.

pyriformis muscle allows a preferential path for the spread of infection from the pelvis to the hip, thigh, and buttock region as demonstrated in this case. The multiplanar imaging capability and unique sensitivity of MR to fluid can be invaluable as demonstrated in this case. MR clearly demonstrated the spread of fluid and air from the sigmoid colon and abscess through the greater sciatic notch to the hip region bilaterally corresponding to the course of the pyriformis muscle.

The clinical presentation of extraperitoneal bowel perforation is confusing and presents a diagnostic challenge to the physician. An understanding and awareness of the anatomy and potential pathways of extraperitoneal spread of extravasated bowel contents will enable a more timely diagnosis, reducing morbidity and mortality. MR can be a uniquely effective means of diagnosing gastrointestinal and abdominal disease as was demonstrated in this case.



Figure 5. Gastrografin® enema showed narrowing of the distal sigmoid colon and extravasation of contrast from the sigmoid colon along the course of the pyriformis muscle bilaterally.

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Transjugular Intrahepatic Portosystemic Shunt (TIPS):

A Promising Nonsurgical Treatment for Bleeding Gastroesophageal Varices

Tim L. Tytle, MD; C. Loeffler, MD; Webb M. Thompson III, MD

Transjugular intrahepatic portosystemic shunts (TIPS) is a relatively new procedure for variceal decompression and alleviation of variceal bleeding. A central connection is made transjugularly between the right hepatic vein and portal vein confluence. The shunt is then buttressed with metallic stents. Between March and August 1992, nine patients with cirrhosis and recurrent variceal hemorrhage have undergone the TIPS procedure at Oklahoma Memorial Hospital. The procedure was successfully performed in all patients. The mean initial direct portosystemic gradient of 22.4 mm Hg was reduced to 9.7 mm Hg. All patients have survived to date with no evidence of recurrent variceal hemorrhage following discharge or transfer. Initial results from our institution and internationally suggest that the TIPS procedure will become an attractive alternative to operative portosystemic shunts.

The treatment of bleeding gastroesophageal varices is a complex problem. The management of these patients requires a multidisciplinary approach with input from the surgical service, gastroenterology, interventional radiology, and social services. While transhepatic variceal embolization has had some success, sclerotherapy and surgically created portosystemic shunts have remained the mainstay of interventional management.

Although sclerotherapy remains the accepted current initial intervention for active variceal bleeding in most patients, it is unsuccessful in 10% to 30% and does not reduce portal pressure; rebleeding is therefore not uncommon.[1-4] Furthermore, sclerotherapy is of little value for the treatment of bleeding gastric varices. Likewise, surgically created portosystemic shunts often carry a high perioperative mortality and have a variable incidence of postoperative encephalopathy.[1,5,6] The increasing popularity of liver transplantation has added an additional factor to be considered in the anatomic location of shunt placements.

In selective patients a new, still-investigational treatment called TIPS (transjugular intrahepatic portosystemic shunt) has added another dimension in the treatment of severe and/or recurrent variceal bleeding. TIPS, in brief, is a means of decompressing the portal system by creating a metallic buttressed shunt between a hepatic vein and the portal system at or near the portal vein confluence.

Historically, the evolution of TIPS procedures is relatively short. In 1969, Rosch et al[7] successfully created an intrahepatic shunt between the inferior vena cava and portal vein in swine. While these shunts showed promise, a device was needed to prevent shunt reocclusion due to the tissue elastic recoil. In 1982, Colapinto and colleagues described the successful creation of a transhepatic portosystemic shunt in a human from a transjugular approach. He kept the transparenchymal track patent by returning the patient for repeated balloon dilatations.[8] With the creation of percutaneously inserted metallic stents, the missing link preventing premature shunt closure was at hand. In 1988, the first TIPS procedure utilizing a balloon-expandable Palmaz stent in humans was successfully performed in Ger-

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many.[9] In 1990 the first similar procedures were performed in the United States by investigators in Miami and San Francisco.[10] The preliminary encouraging reports from these and other institutions led us to initiate the procedure at the University of Oklahoma Health Sciences Center.

Materials and Methods

From March through August 1992, nine TIPS procedures were performed at the University of Oklahoma Health Sciences Center in patients with portal hypertension and bleeding from gastroesophageal varices (Table 1). In each case a preliminary biplane superior mesenteric artery and/or splenic portogram with secondary placement of a catheter guidewire in the right hepatic vein was performed. This allowed evaluation of portal vein patency, a broad estimate of the direction of flow within the portal system, the major portal decompressive pathways, and the anatomic relationship between the portal vein and the selected hepatic vein. The shunt placement, dependent upon need, was performed either immediately following the preliminary procedure or (ideally) at a later date.

Utilizing a right transjugular approach, a 30 cm to 40 cm 10 FR introducer sheath was inserted and advanced into the appropriate hepatic vein. Through this sheath a long sheathed 16-gauge curved-tip needle (Colapinto) was torqued within the selected hepatic vein in the direction of the portal vein confluence (Fig. 1). With the aid of the previous portogram and ultrasound guidance, a smaller, longer 21-gauge needle was advanced through the vein wall and well into the parenchyma. Aspiration was applied to this needle as it was slowly withdrawn. This technique was repeated until venous blood was aspirated. Contrast agent injected through the needle confirmed its location. Once an acceptable location at or very near the portal vein confluence was entered, the Colapinto needle was directed over the 21-gauge needle into the portal system. The 21-gauge needle was then withdrawn and a heavy-duty guidewire advanced well into the central portal system. The Colapinto needle was withdrawn and a 5 FR catheter advanced into the splenic vein. Initial pressure readings were taken through the catheter as well as through the 10 FR sheath within the hepatic vein, yielding an accurate baseline-corrected portal pressure, central venous pressure, and portosystemic gradient. A direct portogram was then performed through the catheter (Fig. 2). The transparenchymal track was subsequently dilated employing an 8 mm balloon catheter. Using the 10 FR sheath, two to four balloon-expandable Palmaz stents over an 8 mm balloon were placed bridging the transparenchymal track. The stents were further expanded as needed until a portosystemic gradient of about 10-12 mm Hg was achieved. A repeat, direct portogram was performed, and all accessible opacifying gastroesophageal varices were ultimately embolized with Gianturio steel coils or ethyl alcohol (Fig. 3). In the first two cases, the embolization through the shunt was performed later in the same hospitalization, following evidence of recurrent upper gastrointestinal hemorrhage.

Results

Transjugular intrahepatic portosystemic shunts have been performed at the University of Oklahoma Health Sciences Center in nine patients without technical failure or periprocedural complication except for one patient with transient sequelae of contrast-induced acute tubular necrosis (Tables 1 and 2). Three patients (#5,#7,#8) have since experienced mild encephalopathy which was successfully treated medically. The average portosystemic pressure gradient prior to the TIPS procedure was 22.4 mm Hg. The postshunt gradient was 9.7 mm Hg with brisk flow through the shunt demonstrated by postprocedural angiography. The shunt diameter was 10 mm in one patient and 12 mm in eight patients. One patient (#8) experienced contrast-related acute tubular necrosis, but recovered completely. All patients were alive without postdischarge recurrent upper gastrointestinal bleeding, three weeks to five months following the TIPS procedure. As previously noted, the first two patients had minor recurrent upper gastrointestinal hemorrhage

Table 1. Demographic and Pre-TIPS Clinical and Laboratory Data

Pt. #	Age (Years)	Sex	Condition	Child's Class	Ascites	Portosystemic Gradient (mmHg)	Ammonia (mmol/L)
1	43	M	Critical	C	None	32	150
2	57	F	Critical	C	Severe	25	48
3	22	F	Stable	B	Mild	11	—
4	39	M	Stable	B	Severe	37	32
5	58	M	Stable	B	None	21	—
6	49	M	Stable	C	None	19	—
7	39	M	Critical	C	None	11	—
8	61	F	Stable	C	Moderate	23	74
9	57	M	Fair	B	Moderate	22.5	56

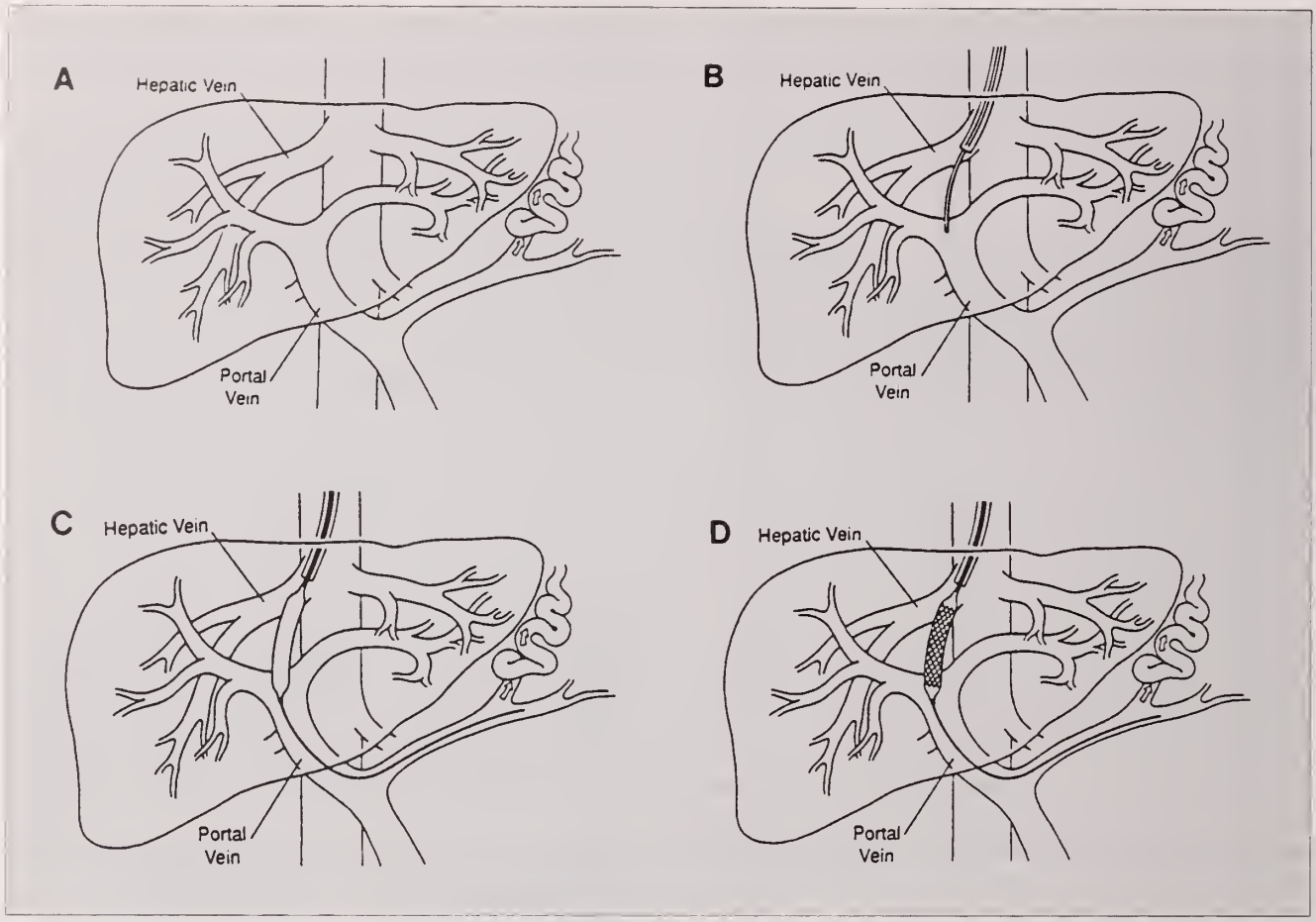


Figure 1. Schematic of TIPS procedure: (A) normal vascular anatomy with right hepatic vein labeled; (B) transgression of hepatic parenchyma between central right hepatic vein and portal vein confluence with Colapinto needle through a sheath; (C) balloon dilatation of parenchymal track; (D) balloon expansion of metallic stent. (Reprinted, in part, from *JAMA*, 17 July 1991, Vol. 266:390-393, Copyright 1991, American Medical Association.)

in the days following the TIPS procedure, necessitating simple reintervention through the shunt with variceal embolocclusion. All shunts are currently patent as evaluated by Duplex Doppler scans.

In a third patient, #8, the initial portosystemic gradient was reduced only to 19 mm Hg. The patient continued to bleed from an ulcer on an incompletely decompressed gastric varix supplied by several small nonembolized short gastric feeders. The patient was returned to the angiographic suite, the feeders were embolized, and the stent dilated to 12 mm, reducing the portosystemic gradient to 12 mm Hg. The patient has not rebled.

Discussion

While sclerotherapy has long been the accepted interventional modality in the treatment of bleeding esophageal varices, its utility in the treatment of bleeding gastric varices and multiple recurrent bleeding esophageal varices is very limited.[2-4] Selective surgically created shunts (i.e., distal splenorenal) have a theoretical advantage over central shunts in that the effect on portal liver perfusion is more limited than with nonselective shunts (i.e., mesocaval or portocaval shunts). This is thought to better protect the liver from rapid further degeneration. However, elective shunt surgery to treat portal hypertension in nonselected patients carries a 5% to 15% mortality rate.[1,5,6] In patients with Child's C, elective shunt creation is associated with a 30% to 40% mortality,[1,5,6,11] and in emergency surgical shunt creation in these patients the mortality rate is 60% to 100%.[1,5,6,11] This does not take into account those patients excluded because of their poor medical status.[9] Two patients (#1 and #7) in our series were actively bleeding and not expected to live more than a few hours. The TIPS procedure, with its very low proce-



Figure 2. Direct splenoportogram following transjugular placement of small caliber catheter transgressing the liver parenchyma between central right hepatic vein and portal vein confluence. Note the large coronary and short gastric veins supplying gastroesophageal varices.



Figure 3. Direct splenoportogram following TIPS procedure. Note coil embolization of varices and decompression of portal system through shunt between portal vein confluence and central right hepatic vein.

dure-related morbidity and mortality rate, would offer a strong alternative in many of these patients. Even some patients with Child's B disease and isolated bleeding gastric varices or bleeding esophageal varices who are not candidates for additional sclerotherapy may benefit from the TIPS procedure.

An additional significant advantage of the TIPS procedure is in potential liver transplant candidates.[10,12,13] The standard portocaval shunts often result in periportal fibrosis complicating the transplant procedure,[9] while functioning distal shunts (splenorenal) must be taken down at or prior to liver transplantation, which significantly lengthens the transplant procedure. By contrast, the TIPS shunt is simply removed with the host liver.

Preliminary data suggest that a portosystemic gradient below 12 mm Hg may be best.[10,14] The therapeutic goal of Richter et al[9] was a mean decrease of 40% of the baseline portal pressure. Too low a shunt gradient may increase the incidence of encephalopathy and accelerate hepatic degeneration, while a gradient which is too high runs the increased risk of recurrent variceal bleeding. An ideal shunt gradient has yet to be established.

While recurrent variceal hemorrhage is unusual following a TIPS procedure, we feel that the added benefit of Gianturio coil (Cook, Inc.) embolization of all accessible variceal feeders once an adequate shunt is in place should further decrease the incidence of recurrent variceal bleeding. To date, we have experienced no recurrent symptomatic variceal bleeding following the hemodynamically adequate TIPS procedure with variceal embolization.

Two major stents have been employed in the TIPS procedure, the self-expanding Wallstent (Schneider) and the Palmaz stent (Johnson-Johnson Interventional Systems Co.). The Wallstent is a more flexible stent, which is easier to insert and has a lower profile. The balloon-expandable Palmaz stent is shorter (3 cm vs. 4.2 cm or 6.8 cm) and is more rigid. However, this stent can be expanded to a diameter significantly greater than the 1 cm maximum diameter of the Wallstent. The Palmaz stent also allows a greater potential for control of the desired portosystemic gradient. In certain situations, both stents may be employed in the same shunt.[16,17] Although this remains a controversial area,[15] we have utilized the Palmaz stent in all patients reported here.

While isolated procedure-produced complications have occurred,

Table 2. Post-TIPS Clinical and Laboratory Data

Pt. #	Ammonia (mmol/L)	Portosystemic Gradient (mm Hg)	Procedural Related Complications	Encephalopathy
1	65	10	None	None
2	40	13	None	None
3	32	6	None	None
4	84	8	None	None
5	97	12	None	Mild
6	139	8	None	None
7	89	9.5	None	Transient
8	33	9	None	Intermittent
9	44	11.5	ATN	None

we are aware of only one procedure-related death. Richter et al[9] reported a procedure-related death as a result of failed embolization of the percutaneous transhepatic access to the portal system. We prefer to avoid transhepatic intervention and, therefore, this potential complication.

With experience, short-term procedure-related complications are minimal. Two long-term complications must be addressed. These are shunt stenosis and occlusion, and an increased incidence of hepatic encephalopathy. Several incidences of shunt-related stenosis and occlusion have been reported.[12,17] These are generally due at least in part to neointimal hyperplasia.[12] Percutaneous reintervention with balloon dilation and occasionally stenting has proven effective.

Encephalopathy, which can occur in up to 30% of patients with surgically created portocaval shunts,[12] is a potential complication. The TIPS shunt is better controlled and generally about half the diameter of the portocaval shunt. Approximately 10% of TIPS patients at the University of California, San Francisco, developed encephalopathy. This was successfully treated with medical therapy in all patients.[12] As previously noted, we have had three patients who developed mild encephalopathy at varying times following this procedure. All were successfully treated with diet control and oral lactulose.

One must not lose sight of the primary goal of the TIPS procedure, that is, to prevent recurrent variceal bleeding with a minimum of morbidity and mortality. Richter et al[6] report no recurrent variceal bleeding in nine patients. Zemel et al[10] describe a solitary rebleed among their eight patients; the bleeding was alleviated by dilating the shunt. La Berge[12] reports that one patient rebled at 102 days following shunt placement. The shunt was found to have occluded.

In academic medicine, even more than in private practice, the physician is exposed to a never-ending avalanche of "promising" new modalities. Preliminary results often form the backbone of many scientific journals. Most fail to withstand the test of time. However, occasionally a procedure graduates to widespread acceptance. We feel that the TIPS may be such a procedure.

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Symposium on Antimicrobial Therapy
VIII. Trimethoprim-Sulfamethoxazole and the Tetracyclines

Ronald A. Greenfield, MD

This is the eighth paper in Dr. Greenfield's symposium on antimicrobial therapy, begun last October.

This segment discusses two unrelated groups of drugs. The major similarity between the two groups is that they are antimicrobial agents which have been important components of oral antimicrobial therapy for many years. The first discussion will be primarily about trimethoprim-sulfamethoxazole, although some discussion of the uses of the individual components will follow description of the combination. Then the tetracycline family will be discussed.

Trimethoprim-sulfamethoxazole has been available for 25 years. It is also known as cotrimoxazole and by the trade names Bactrim® and Septra®. It is available as a fixed ratio combination of trimethoprim to sulfamethoxazole at a ratio of 1 to 5. This is designed to achieve a ratio of 1 to 20 in serum, which approximates the optimal ratio of the two antimicrobial agents for in vitro synergy. Sulfamethoxazole was chosen from the sulfonamides to be combined with trimethoprim because its pharmacokinetic properties most closely resemble those of trimethoprim.

The mechanisms of antimicrobial activity of trimethoprim-sulfamethoxazole are diagrammed in Figure 1.[1,2] They are based on the fact that microorganisms must synthesize tetrahydrofolic acid de novo from paraaminobenzoic acid and pteridine, whereas mammals

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Table 1. In Vitro Antimicrobial Activity of Trimethoprim-Sulfamethoxazole

Organisms usually susceptible to trimethoprim-sulfamethoxazole
Staphylococcus aureus (methicillin-sensitive)
Haemophilus influenzae
Escherichia coli
Proteus mirabilis
Klebsiella — Enterobacter species
Citrobacter diversus
Vibrio cholerae
Yersinia pestis
Pseudomonas cepacia
Chlamydia trachomatis
Pneumocystis carinii
Organisms with variable sensitivity to trimethoprim-sulfamethoxazole
Staphylococcus aureus (methicillin-resistant)
Streptococcus pyogenes
Streptococcus pneumoniae
Neisseria species
Salmonella species
Shigella species
Serratia marcescens
Brucella species
Yersinia enterocolitica
Mycobacterium fortuitum — chelonei
Organisms usually resistant to trimethoprim-sulfamethoxazole
Pseudomonas aeruginosa
Xanthomonas maltophilia
Mycobacterium species other than *M. fortuitum — chelonei*
Treponema pallidum
Ureaplasma species
Mycoplasma species

can assimilate dihydrofolic and tetrahydrofolic acids from foodstuffs. Tetrahydrofolic acid is one of several cofactors essential for many vital biosynthetic reactions, serving as a carrier for one carbon fragments. The most important of these is the synthesis of thymidine, which is an essential purine nucleotide for DNA synthesis. As shown in Figure 1, sulfamethoxazole and trimethoprim inhibit sequential steps in the synthesis of tetrahydrofolic acid. The combined inhibition of this pathway is likely bactericidal in vitro for susceptible pathogens.

A number of mechanisms of resistance to trimethoprim or sulfamethoxazole or both have been described.[3] Intrinsic resistance typically involves detoxification of the antimicrobial, poor antimicrobial penetration, or an absence of drug-sensitive bacterial target sites. Acquired resistance involves mutation to impaired penetration, mutation of target sites to become drug insensitive, hyperproduction of reaction intermediates or enzyme targets, or thymidine auxotrophy. It is important to note that many of the acquired resistance mechanisms are plasmid-mediated and therefore are readily transferable.

Trimethoprim and sulfamethoxazole demonstrate first-order kinetics of absorption, distribution, metabolism, and excretion.[3] Both agents are well absorbed after oral administration. Peak serum levels are achieved after 1 to 4 hours and are 1 µg/ml of trimethoprim and 20 µg/ml of sulfamethoxazole after administration of a dose of 80/400 mg. With repeated dosing every 12 hours, a steady state about 50% higher is achieved. Intravenous administration of the same dose results in trimethoprim levels about twice those with oral dosing and sulfamethoxazole levels that are about 25% higher than those achieved with equal oral dosing. The half-lives of both drugs in individuals with normal renal function are 8 to 12 hours. About half of each dose is excreted in the urine: the trimethoprim is microbiologically active but 80% of the sulfamethoxazole is inactive (due to hepatic metabolism). Both agents, but particularly trimethoprim, penetrate body spaces well, including cerebrospinal fluid. Dosage should be modified for renal insufficiency[2]: if the creatinine clearance is <30 ml/min but >15 ml/min, the dosage should be reduced by half. For patients with creatinine clearance <15 ml/min, the percentage of normal renal function should be multiplied by the normal loading dose to determine the optimal daily dose. Patients on hemodialysis should receive a normal loading dose after each dialysis. Serum concentrations of both trimethoprim and sulfamethoxazole can be measured by specialized laboratories.

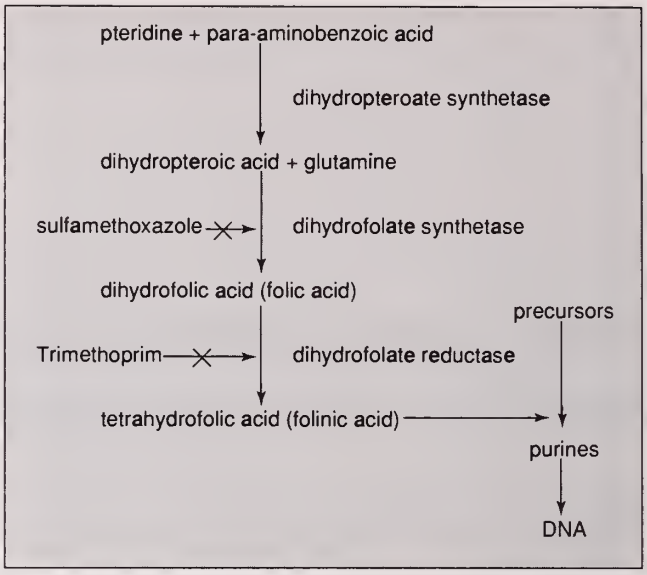


Figure 1. Diagrammatic representation of the mechanisms of action of trimethoprim and sulfamethoxazole. In the pathway for synthesis of tetrahydrofolic acid, sulfamethoxazole inhibits the step catalyzed by dihydrofolate synthetase and trimethoprim inhibits the step catalyzed by dihydrofolate reductase. Tetrahydrofolic acid serves as a cofactor for one carbon transfer reactions, such as the one shown that is essential for DNA synthesis.

Before discussing the clinical usefulness of trimethoprim-sulfamethoxazole, let us first consider adverse reactions to the drug. The most common adverse reactions are upper gastrointestinal symptoms and skin rashes, which have been reported to occur in about 3% of the general population receiving the drug.[2] Megaloblastic changes, anemia, leukopenia, and thrombocytopenia are unusual unless the patient has preexistent marginal folate or vitamin B_{12} stores. Intrahepatic cholestasis[4] and acute pancreatitis[5] have been uncommonly associated with trimethoprim-sulfamethoxazole. In patients with AIDS, skin rashes, hematologic toxicity, and hepatotoxicity are distinctly more common, occurring in 30% to 70% of patients receiving trimethoprim-sulfamethoxazole.[2] Administration of tetrahydrofolic acid (folinic acid, leukovoran) may minimize the hematologic toxicity of trimethoprim-sulfamethoxazole in AIDS patients, without negating therapeutic efficacy. Therapy is also rarely associated with aseptic meningitis.[6] Trimethoprim-sulfamethoxazole should be avoided in pregnancy: trimethoprim is potentially teratogenic and sulfonamides displace bilirubin from albumin and thus promote kernicterus. Trimethoprim is a competitive inhibitor of creatinine excretion and can rarely lead to an elevation of serum creatinine that does not reflect an impaired glomerular filtration rate.

The drug can potentiate the effects of warfarin, phenytoin, tolbutamide, chlorpropamide, and procainamide and N-acetylprocainamide.[7,8] Very rarely, and usually in patients with impaired renal function treated with high doses, sulfamethoxazole can produce crystalluria.

The remainder of this discussion will focus on the clinical usefulness of trimethoprim-sulfamethoxazole. The most common use of trimethoprim-sulfamethoxazole is in the treatment of genitourinary tract infections. Trimethoprim-sulfamethoxazole is active against the overwhelming majority of community-acquired urinary tract infections, and its favorable side-effect profile and cost make it a reasonable drug of first choice in this infection. For uncomplicated cystitis in young females, a short course regimen of two double strength tablets (each double strength tablet contains 160 mg of trimethoprim and 800 mg of sulfamethoxazole) as a single dose has been shown to be effective. Otherwise, conventional therapy for urinary tract infection is one double strength tablet every 12 hours for 7 to 10 days.[2] A single strength tablet once daily has been demonstrated effective against recurrent urinary tract infections in females.[9] Although effective against chronic bacterial prostatitis, I believe this role is now better filled by a fluoroquinolone. Likewise, several regimens of trimethoprim-sulfamethoxazole therapy have been established as effective therapy for uncomplicated gonorrhea, but a variety of more useful regimens exist. Trimethoprim-sulfamethoxazole is a useful alternative regimen for nongonococcal urethritis and cervicitis; lack of activity against Ureaplasma species prohibits a role as a first line agent. Also, trimethoprim-sulfamethoxazole is likely inactive in treatment of syphilis, which decreases its value in treatment of sexually transmitted diseases. Trimethoprim-sulfamethoxazole is an alternative treatment for chancroid (*Haemophilus ducreyi* infection), lymphogranuloma venereum, and donovanosis (granuloma inguinale).[10]

Although trimethoprim-sulfamethoxazole was once widely used for prophylaxis and treatment of traveler's diarrhea and other bacterial intestinal infections, including salmonellosis and shigellosis, emergence of resistance, perhaps largely resulting from its use for this indication, now makes fluoroquinolone therapy preferred. The use of fluoroquinolones in this setting has been reviewed earlier in this symposium.

The activity of trimethoprim-sulfamethoxazole against most strains of *Streptococcus pneumoniae* and *Haemophilus influenzae* makes it a useful agent for treatment of acute otitis media, sinusitis, bronchitis, and pneumonitis.[2] For adults, a double strength tablet every twelve hours for 7 to 10 days is reasonable for this indication. Trimethoprim-sulfamethoxazole is a poorer alternative to penicillin and the macrolides for treatment of acute streptococcal pharyngitis. Trimethoprim-sulfamethoxazole is an inferior alternative to ampicillin or amoxicillin for treatment of acute infectious exacerbations of chronic bronchitis, but it is an alternative in patients allergic to penicillins.[11]

Trimethoprim-sulfamethoxazole has a variety of uses for less common infections. Trimethoprim-sulfamethoxazole is the treatment of first choice for *Pneumocystis carinii* infection, including patients with AIDS with this infection.[12] The recommended dose for treatment of *P. carinii* pneumonia is 20 mg/kg/day of the trimethoprim component, divided into 4 doses administered intravenously or orally. For patients with AIDS, treatment should be continued for 3 weeks; a treatment course of 2 weeks may be sufficient for other patient groups. Trimethoprim-sulfamethoxazole has become the preferred regimen for prophylaxis of *P. carinii* pneumonia in patients with HIV infection and a CD4+ cell count less than 200/mm^3: one double strength tablet daily is the preferred regimen.[13] This regimen may also reduce the incidence of other infections in AIDS patients, including toxoplasmosis. Trimethoprim-sulfamethoxazole (10-15 mg/kg/day of the trimethoprim component) is a treatment of choice for nocardiosis,[14] although in my opinion, never convincingly demonstrated more effective than sulfadiazine alone. Some strains of methicillin-resistant *Staphylococcus aureus* are susceptible in vitro to trimethoprim-sulfamethoxazole; in these situations it is a valuable treatment alternative. Trimethoprim-sulfamethoxazole is a therapy of choice for *Pseudomonas cepacia* infections, and an alternative treatment regimen for brucellosis.[2] Trimethoprim-sulfamethoxazole is the treatment of choice for gastrointestinal infection with the protozoan *Isospora belli.*[15] Although a pathogen has not been identified, trimethoprim-sulfamethoxazole has proven beneficial in some patients with Wegener's granulomatosis.[16] Trimethoprim-sulfamethoxazole has been used for prevention of aerobic Gram-negative bacillary infections in patients with neutropenia, but this role has largely been supplanted by fluoroquinolones. Long-term prophylaxis with trimethoprim-sulfamethoxazole is beneficial for patients with chronic granulomatous disease of childhood.[17]

Only a few indications remain for treatment with a sulfonamide alone. Because of the convenience of twice-daily administration of trimethoprim-sulfamethoxazole and its relative low cost, sulfonamide therapy alone is

rarely considered. As noted above, one exception is the treatment of nocardiosis, in which some prefer therapy with sulfadiazine. Another important use of sulfadiazine in the AIDS era is for treatment of toxoplasmosis, in combination with pyrimethamine. Sulfadiazine is also a treatment of choice for paracoccidioidomycosis,[18] a fungal infection that does not occur endemically in the U.S. A combination of erythromycin and sulfisoxazole is marketed as Pediazole®: this drug has no usefulness in adults and I claim no expertise in pediatrics, so no further discussion of this combination will ensue.

There are perhaps even fewer situations in which to consider the use of trimethoprim alone. In fact, the only use I can think of is in combination with dapsone as an alternative treatment for *Pneumocystis carinii* pneumonitis.[19] In this situation, 20 mg/kg/day of trimethoprim, in four divided oral doses, is given in combination with 100 mg orally per day of dapsone, which is a sulfone antimicrobial. Many patients allergic to trimethoprim-sulfamethoxazole can be successfully treated with trimethoprim and dapsone. Dapsone should not be administered to patients with glucose-6-phosphate dehydrogenase deficiency, as hemolysis may result; appropriate patient groups should be screened for this deficiency before dapsone therapy is initiated.

The Tetracyclines

The tetracyclines, discovered initially from *Streptomyces aureofaciens,* are a family of broad-spectrum antibiotics that have activity against aerobic and anaerobic Gram-positive and Gram-negative bacteria, spirochetes, mycoplasmas, rickettsiae, chlamydiae, and some protozoa. They can be divided into three groups on the basis of pharmacologic properties. The short-acting tetracyclines are **chlortetracycline, tetracycline,** and **oxytetracycline.** The first tetracycline available, chlortetracycline (aureomycin), is no longer marketed in the U.S. There are no significant differences in antimicrobial activity among the three short-acting tetracyclines. In view of that statement, cost factors preclude the use of oxytetracycline. Thus tetracycline (technically, tetracycline hydrochloride) is the only short-acting tetracycline that will be discussed further. A tetracycline phosphate complex is available but of no established advantage. The intermediate-acting tetracyclines are **demeclocycline** and **methacycline.** There is no role in the antimicrobial armamentarium for either of these intermediate-acting tetracyclines. Demeclocycline is, however, occasionally useful for the treatment of the syndrome of inappropriate secretion of antidiuretic hormone (SIADH).[20] There are two long-acting tetracyclines: **minocycline** and **doxycycline.** These two are useful antimicrobial agents.

The tetracyclines are primarily bacteriostatic antibiotics. To exert their antimicrobial effect, tetracyclines must first accumulate in the bacterial cytosol. This is achieved by an initial rapid diffusion phase and a slower second phase accomplished by active transport.[21] The tetracyclines then bind to the 30S ribosomal subunit at a position that blocks the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA-ribosome complex, inhibiting the addition of new amino acids onto the growing peptide chain, thus inhibiting protein synthesis.[21] There are several mechanisms of bacterial resistance to tetracyclines[22]: (1) some bacteria possess an efflux type of resistance gene, the product of which pumps tetracyclines out of the cell, disabling accumulation of adequate concentrations of drug; (2) some bacteria possess a ribosomal protection gene, the product of which interacts with ribosomes in such a way that protein synthesis proceeds despite high concentrations of tetracyclines; and least commonly (3) some bacteria possess a gene encoding a tetracycline-inactivating enzyme. In general, these resistance mechanisms equally affect all available tetracyclines and are transferable among bacteria.[22]

Although many bacterial pathogens in humans are within the in vitro spectrum of activity of the tetracyclines, which were a mainstay of oral antimicrobial therapy of infections in adults in the 1950s and 1960s, resistance to tetracyclines has developed and spread, and more effective agents are now available for many of these microorganisms.[21] Many pneumococci and *H. influenzae* are inhibited by tetracyclines, but resistance to these common respiratory pathogens is increasingly problematic. The frequency with which gonococcal resistance to tetracyclines is currently encountered now *precludes* the use of these agents for treatment of gonorrhea.[10] Most community acquired *E. coli* infections are susceptible to tetracyclines. Important activity among other aerobic Gram-negative bacilli is limited to *Pseudomonas pseudomallei,* Brucella species, and Vibrio species. The tetracyclines, and particularly doxycycline, have considerable activity against anaerobic bacteria, but this activity is *inferior* to that of clindamycin or metronidazole. The tetracyclines are active against pathogenic spirochetes including Treponema species (*T. pallidum* is the causative agent of syphilis), the various species of Leptospira, and *Borrelia burgdofferi* (the causative agent of Lyme disease). Most species of Mycoplasma and Ureaplasma and most chlamydiae and rickettsiae are inhibited by tetracy-

clines. Tetracyclines have clinically important activity against the protozoan pathogens of malaria and amebiasis.

The pertinent pharmacology of the tetracyclines can be summarized as follows.[21,23] Tetracycline is 60% to 80% absorbed after oral administration. Absorption is drastically reduced by concomitant administration of antacids, milk, calcium and magnesium salts, iron preparations, and likely by increase in gastric pH. The absorption of doxycycline and minocycline after oral administration is essentially complete and not reduced by concomitant foodstuffs. Peak serum levels after 500 mg of tetracycline or 200 mg of doxycycline or minocycline are achieved 2 hours after oral administration and are 3 to 5 μg/ml. Intravenous administration of these doses achieves serum levels of 10 to 20 μg/ml. Tetracycline has a serum half-life of 8 hours; the half-lives of minocycline and doxycycline are 16 to 18 hours. Tetracyclines are metabolized by the liver and concentrated five- to ten-fold in the bile, in the absence of biliary obstruction. Tetracyclines achieve adequate concentrations in all body fluids except cerebrospinal fluid. All tetracyclines achieve urinary concentrations adequate for treatment of urinary tract infections. Minocycline is unique among tetracyclines (and relatively unique among all antimicrobial agents) in achievement of relatively high concentrations in saliva, largely due to its lipophilicity. Doxycycline does not require dosage modification in patients with renal insufficiency; usage of other tetracyclines should be avoided in patients with renal insufficiency. Dosage of all tetracyclines should be reduced in patients with severe hepatic insufficiency.

The emergence and spread of resistance to tetracyclines has limited their usefulness in the past 20 years; however, they remain a quite useful class.

Tetracyclines are indicated for a variety of infections.[21,23] Generally, either tetracycline hydrochloride (250-500 mg PO q6h) or doxycycline (200 mg, then 100 mg PO q12h) is indicated in the settings described below, unless otherwise specified. In most situations, tetracycline remains the cheaper alternative, but with the cost differential relatively small and continuing to decrease, many prefer to use doxycycline. This avoids many of the concerns about concomitant food administration. When a parenteral tetracycline is indicated, and this is relatively rare, doxycycline is generally preferred because of the propensity of intravenously administered tetracycline to produce thrombophlebitis (a property used to advantage for sclerosing intrapleural therapy).

Tetracyclines are a therapy of choice for all chlamydial infections, which include nongonococcal urethritis/cervicitis, lymphogranuloma venereum, trachoma, and psittacosis. Tetracyclines are a therapy of choice for the acute urethral syndrome (dysuria-frequency syndrome) in young females.[24] Tetracyclines are a therapy of choice for all rickettsial infections, although some prefer chloramphenicol for severe Rocky Mountain spotted fever. Tetracyclines are a therapy of choice for treatment of brucellosis, in combination with streptomycin in seriously ill patients. Tetracyclines are a treatment of choice for cholera and other Vibrio species infections, donovanosis, meliodosis, leptospirosis, and relapsing fever. Tetracyclines are effective therapy for *Mycoplasma pneumoniae* infections, although erythromycin may be preferable. Tetracyclines are effective for early Lyme disease. Minocycline is effective therapy for nocardiosis (usually in combination with other agents), for treatment of *Mycobacterium marinum* infections, and for prophylactic therapy of the meningococcal carrier state. Tetracyclines are effective alternative therapy for severe acne, actinomycosis, anthrax, acute infectious exacerbations of chronic bronchitis, syphilis (except neurosyphilis), tularemia, and Vincent's angina. Tetracyclines are effective therapy for some patients with Whipple's disease.

It is important for prescribing physicians to be aware of the toxicity profile of these commonly used antibiotics. A variety of hypersensitivity reactions to the tetracyclines occur, but are uncommon: anaphylaxis, urticaria, periorbital edema, fixed drug eruptions, and morbilliform rashes all have been reported. An allergic reaction to any tetracycline should be considered as a contraindication to the use of any member of the family. A photosensitivity rash occurring on exposed areas is fairly common with administration of any of the tetracyclines.

The effects of tetracyclines on teeth and bones are widely known. Tetracyclines are generally to be avoided in children because they may cause permanent darkening of the teeth associated with hypoplasia of the

enamel. Because tetracyclines cross the placental barrier, their usage is also to be avoided in pregnant women. Tetracyclines may also depress skeletal growth in children. These effects are generally related to duration of tetracycline therapy, and therefore, in certain circumstances, tetracyclines may be used for treatment of life-threatening infections in children, when toxicity of alternative therapy exceeds the risk of tetracycline therapy. Such a decision, however, requires pediatric expertise not possessed by this author.

Gastrointestinal irritation, in the form of both upper gastrointestinal upset and diarrhea, is fairly common with tetracyclines. Doxycycline may cause less diarrhea than tetracycline hydrochloride. Hepatotoxicity, in the form of fatty necrosis, has been reported with tetracyclines, and is distinctly more common in pregnant women (therefore this is a second reason to avoid the use of these drugs in pregnant women), in patients given more than 2 gm/d of intravenous tetracycline, and in patients with renal insufficiency given high dose tetracycline therapy. The effect of tetracyclines on inhibition of protein synthesis results in a catabolic effect, which increases azotemia (manifested as an increased blood urea nitrogen) when tetracycline is administered to patients with renal insufficiency. As previously noted, doxycycline is clearly preferred among the tetracyclines for treatment of infections in patients with renal insufficiency. Vestibular toxicity, which can be manifested as vertigo, dizziness, ataxia, nausea, and vomiting, is a common, albeit transient, side effect unique to minocycline, and severely limits the usefulness of this drug. All tetracyclines have been associated with the production of benign intracranial hypertension. Alterations in normal vaginal flora frequently result in the development of vaginal candidiasis in women treated with tetracyclines.

Finally, there are some noteworthy drug interactions with tetracycline administration. Inhibition of tetracycline absorption by divalent and trivalent cations has been previously mentioned. Phenytoin, barbiturates, and carbamazepine all can decrease the therapeutic efficacy of doxycycline by increasing its hepatic metabolism. Women have become pregnant while using oral contraceptives for pregnancy prevention concurrent with tetracycline administration; this presumably results from a reduction in bacterial hydrolysis of conjugated estrogen in the intestine.

The emergence and spread of resistance to tetracyclines has limited their usefulness in the past 20 years; however, they remain a quite useful class. It is possible that further development of this family, in the form of chelocardin-type tetracyclines, which appear to exert a different antimicrobial effect and resist current types of tetracycline resistance, will lead to the development of useful new tetracycline congeners.

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Cigarette Smoking Among Women in Oklahoma: Before, During, and After Pregnancy

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Data from the Oklahoma Pregnancy Risk Assessment Monitoring System (PRAMS) were assessed to determine the prevalence of maternal cigarette smoking and its relationship to pregnancy outcomes. A mail and telephone questionnaire was used to survey mothers between four and six months postpartum to obtain information about smoking and other maternal behaviors. Monthly samples were drawn from the state's live birth registry utilizing a systematic stratified sampling approach based on infant birth weight. A total of 3,051 responses were received between 1988 and 1990 for an overall return rate of 70%. Results of the study show approximately one-third (32%) of women in Oklahoma smoked 3 months prior to pregnancy, 22% smoked in their last 3 months of pregnancy, and 29% smoked shortly after delivery. Women who smoked during pregnancy were 2.2 times more likely to deliver a low birth weight (LBW) infant than nonsmokers, and 1.4 times more likely to have gained less than the recommended amount of weight. Additionally, women who smoked during pregnancy were 1.4 times more likely to begin prenatal care in the second or third trimester, or to receive no care at all. In conclusion, maternal smoking cessation has the potential for dramatically reducing preventable adverse outcomes of pregnancy.

Cigarette smoking during pregnancy increases the risk of delivering a LBW infant (LBW is defined as infants weighing less than 5.5 pounds or 2,500 grams at birth). LBW is a leading indicator of infant mortality and morbidity, and women who smoke deliver LBW infants twice as often as nonsmokers.[1]

Studies of other effects of maternal smoking on offspring have been inconclusive. Whereas some investigators have found a higher incidence of congenital malformations (neural tube defects, anencephaly, cleft palate, congenital heart defects, and limb reduction defects), others have not.[2] Studies have also indicated that incidences of fetal, neonatal, and perinatal mortality are higher in women who smoke during pregnancy.[3] Regardless of other effects, the intensity of care necessary for underweight infants alone requires excessive public and private expenditures. These costs could be dramatically decreased if mothers were to abstain from smoking while pregnant.

In the past, little information has been available on the prevalence of maternal smoking in Oklahoma. Organizations interested in maternal smoking cessation projects have previously relied on national surveys or information from other states as guides for planning. In an effort to provide health care providers in Oklahoma with information about smoking and other pregnancy risk factors, the Pregnancy Risk Assessment Monitoring System (PRAMS) survey was implemented.

Methods

A stratified systematic sampling approach, based on four categories of birth weight, was used to select approximately 175 state resident mothers each month from the live birth registry in Oklahoma. The average

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age of infants at the time of selection was five months. Oversampling occurred among mothers whose deliveries were very low birth weight (<1,500 g; 1:1), moderately low birth weight (1,500-2,499 g; 1:5) and high birth weight (≥4,000 g; 1:8). Normal probability sampling was used for mothers delivering normal birth weight infants (2,500-3,999 g; 1:59). Sampling exclusions included mothers whose infants were placed for adoption, infants younger than 3 months or older than 6 months, and infants whose birth certificates were lacking the mother's name or address. Up to three questionnaires were mailed to solicit a response. Telephone interviews were attempted for non-responders. At the time of analysis, 3,051 of 4,300 mothers had responded, for an overall response rate of 70%. Sample selections represent women giving birth between April 1988 and March 1990. The average survey was completed at six months postpartum. Questionnaires were linked to birth certificate data for outcome and demographic information. Point estimates and their standard errors were calculated using SUDAAN software. Chi-square tests were performed to test the differences in the proportion of adverse pregnancy outcomes between smokers and nonsmokers. Standard errors were provided to calculate 95% confidence intervals.

PRAMS Questions Related to Smoking

15. When you went for prenatal care, did a doctor, nurse, or other health worker ask if you were smoking?	____No ____Yes
16. Did a doctor or nurse talk to you about how smoking during pregnancy could affect your baby?	____No ____Yes
27. In the **3 months before** you got pregnant, how many cigarettes or packs of cigarettes did you smoke on an average day? (A pack has 20 cigarettes)	____Cigarettes or____packs () Less than 1 () Didn't smoke () Don't know
28. In the **last 3 months** of your pregnancy, how many cigarettes or packs of cigarettes did you smoke on an average day?	____Cigarettes or____packs () Less than 1 cig/day () Didn't smoke () Don't know
29. How many cigarettes or packs of cigarettes do you smoke on an average day **now**?	____Cigarettes or____packs () Less than 1 cig/day () Don't smoke () Don't know

Figure 1. PRAMS questions related to smoking.

Five questions were used to assess pregnancy-related smoking (Fig. 1). Two questions asked whether prenatal care providers typically questioned and advised mothers about cigarette smoking during pregnancy. The remaining three questions were designed to ascertain the amount and frequency of smoking in the three months prior to pregnancy, during the last three months of pregnancy, and at the time of questionnaire completion. Additional questions were used to assess time of recognition of pregnancy, prenatal care entry, and maternal weight gain. Women with unknown values were excluded from analysis. Because data used for this study are self reported and results are derived from univariate and bivariate analyses, they should be interpreted cautiously.

Results

Prevalence of Smoking. Approximately one-third (32%) of women in Oklahoma indicated that they smoked during the three months prior to pregnancy (Fig. 2). By the last three months of pregnancy, the proportion decreased to 22%. However, rates of beginning to smoke again after delivery were high; of the women who smoked before pregnancy, 90% smoked after delivery. Overall, 29% of all mothers smoked after delivery.

Analysis of pre-pregnancy smoking levels indicated that nearly 6% of all women smoked at least 40 cigarettes daily, 13% between 20 and 39 cigarettes, and 12% less than 20 cigarettes per day (Table 1). During the last three months of pregnancy, 2% of women smoked 40 or more cigarettes daily, 7% smoked between 20 and 39 cigarettes, and 12% smoked less than 20 cigarettes per day.

Among pre-pregnancy smokers, the median number of cigarettes smoked per day was 19 (women re-

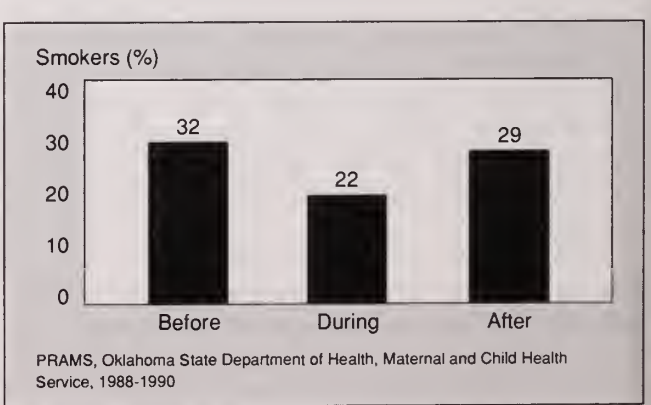


Figure 2. Percent of women smoking cigarettes before, during, and after pregnancy.

porting less than one cigarette per day were counted as smoking one cigarette per day). Among women who smoked during the last three months of pregnancy, the median number of cigarettes per day was 13 (data not shown). National data from the 1985 to 1988 Behavioral Risk Factor Survey (BRFS) indicate a median of 20 cigarettes per day among non-pregnant smokers and 12 cigarettes per day among pregnant smokers.[4]

Pregnancy Outcome Among Smokers and Nonsmokers. Pregnancy outcomes were compared between women who smoked and women who did not smoke during the last three months of pregnancy. Smokers were 2.2 times more likely to deliver a LBW infant than nonsmokers (Table 2). The proportion of LBW infants born to nonsmokers was 4.9%. Full-term (37 weeks or greater gestation) infants born to smokers weighed, on the average, 255 grams (one-half pound) less than infants of nonsmokers. Between smokers and nonsmokers, the difference in birth weight was greatest for blacks (645 grams or 22.8 ounces), and least for American Indians (108 grams or 3.8 ounces), while the difference in birthweight for whites was 298 grams or 10.6 ounces (data not shown). Slight differences were found in gestational age at delivery. Smokers had a higher proportion of deliveries prior to 37 weeks gestation; however, differences were not statistically significant.

Based on the recommendations for total weight gain of the National Academy of Science,[5] a greater percentage of smokers (30%) than nonsmokers (20%) gained under the recommended amount of weight ($p < .05$). Nonsmokers (44%) were more likely than smokers (33%) to gain within the recommended amount of weight ($p < .05$).

Health Care Characteristics Among Smokers and Nonsmokers. Smokers were less likely than nonsmokers to recognize their pregnancies at an early stage, a factor that could influence early entry into prenatal care (Table 3). Women who smoked during the last 3 months of pregnancy were more likely than nonsmokers to be unaware of their pregnancy until 13 weeks or more gestation. Among women who recognized that they were pregnant within the first 4 weeks of pregnancy, 80% were nonsmokers and 20% were smokers. In contrast, of those women who recognized that they were pregnant at 14 or more weeks of pregnancy, 66% were nonsmokers and 34% were smokers.

The timing of prenatal care entry also varied with smoking status. Smokers were more likely than nonsmokers to begin care in the second or third trimester or to receive no care at all. Of those who received first trimester care, 80% were nonsmokers and 20% were smokers; of those who delayed care until after the first trimester or never received care, 73% were nonsmokers and 28% were smokers.

Slight differences were also found with smoking status and adequacy of prenatal care. Based on the Ade-

Table 1. Distribution of Smoking in the Three Months Before Pregnancy and During the Last Three Months of Pregnancy by Smoking Status

Smoking Status	3 Months Before Pregnancy (*N*=3051)	(95% CI)	Last 3 Months of Pregnancy (*N*=3051)	(95% CI)
Nonsmoker	64.3	(61.6-67.0)	74.4	(71.9-76.9)
Light	5.2	(3.8- 6.6)	5.6	(4.2- 7.0)
Moderate	6.8	(5.2- 8.4)	6.0	(4.5- 7.3)
Heavy	12.5	(10.5-14.5)	7.2	(5.6- 8.8)
Ultra heavy	5.9	(4.5- 7.3)	2.1	(1.3- 2.9)
Don't know/missing	5.3	(3.9- 6.7)	4.7	(3.5- 5.9)

Light smokers were defined as those smoking 1-9 cigarettes per day; moderate included 10-19 cigarettes per day; heavy ranged from 20-39 cigarettes per day; and ultra-heavy defined as 40 or more cigarettes per day.

Table 2. Pregnancy Outcomes* Among Smokers During the Last Three Months of Pregnancy and Nonsmokers

Characteristic	Nonsmokers % (*N* = 2222)	(95% CI)	Smokers % (*N* = 676)	(95% CI)
Birth Weight				
Under 2500 g	4.9	(4.7- 5.1)	11.0	(9.4-12.6)
Gestational Age				
Under 37 weeks	10.9	(8.7-13.1)	12.9	(8.4-17.4)
Weight Gain**				
Under recommended	20.5	(17.6-23.4)	29.6	(23.3-35.9)
Within recommended	43.9	(40.4-47.4)	32.8	(26.3-39.3)
Over recommended	35.6	(32.3-38.9)	37.6	(30.9-44.3)

*Mothers with multiple births were excluded from analysis.

**The National Academy of Sciences total weight gain ranges for pregnant women by prepregnancy body mass index were used as the standard for weight gain. Women at 40 or more weeks gestation were evaluated based on three prepregnancy BMI categories of expected weight gain: Low (<19.8), 28 to 40 pounds; Normal (19.8 to 26.0), 25 to 35 pounds; High (>26.0 to 29.0) 15 to 25 pounds. The ranges for women at 40 or fewer weeks gestation were extrapolated according to clinical estimates for weight gain.[6] Excludes data on women for whom last date of menses or BMI were unknown.

quacy of Prenatal Care Utilization (APCU) Index (Kotelchuck's revision of the Kessner Prenatal Care Utilization Index),[7] smokers were more likely than nonsmokers to receive inadequate care. Of those who received adequate care, 80% were nonsmokers and 20% were smokers. Comparatively, of those who received inadequate care, 74% were nonsmokers and 26% were smokers.

The majority of smokers are seen in private settings. However, public prenatal care clinics in health departments served, proportionally, the greatest concentration of clients who smoked. Whereas 37% of health department clients smoked, 22% of Indian Health Service, 21% of hospital clinic, and 21% of private physicians' or HMO clients smoked cigarettes during the last three months of pregnancy.

Differences in method of payment for prenatal care were also found with respect to prenatal smoking status. A larger percentage of clients whose prenatal care was funded by Medicaid were smokers (37%) than clients who received free treatment (31%), paid cash only (25%), received care at the Indian Health Service clinics (21%), or held private or group insurance (15%).

Prevalence of Smoking by Maternal Demographic Characteristics. Examination of age differences showed the highest proportion of pre-pregnancy and prenatal smokers to be among women aged 25 and under, while the lowest was mothers aged 35 and over (Table 4). Teens were nearly twice as likely to smoke during pregnancy as women aged 35 and over. Teens were also more likely (47%) than women aged 35 and over (24%) to be pre-pregnancy smokers.

Assessment of educational attainment showed the proportion of women who smoked during the last three months of pregnancy to be highest among those with 12 or fewer years of formal education. Women who had not completed high school were 7.3 times more likely to smoke, and women with high school degrees were 4.8 times more likely to smoke than women with college degrees.

White women were nearly 2.5 times as likely to smoke before (p <.01) and during (p <.01) pregnancy as black women. Thirty-three percent of white women smoked before and 23% smoked during pregnancy, whereas 14% of black women smoked before and 9% smoked during pregnancy.

Examination of marital status revealed strong differences with respect to maternal smoking. More than half of unmarried women smoked prior to pregnancy. Unmarried women were nearly twice as likely to smoke during the last three months of pregnancy as married women.

Discussion of Maternal Smoking by Provider. Nearly 95% of mothers surveyed indicated that their prenatal care provider questioned them about their smoking behavior (Table 5). Among women who smoked during the last three months of pregnancy, only 4.7% indicated that their provider did not

Table 3. Smoking Prevalence Rates by Health Care Characteristics Among Smokers During the Last Three Months of Pregnancy and Nonsmokers

Characteristics	Nonsmokers %	(95% CI)	Smokers %	(95% CI)
Pre-pregnancy Weight				
Underweight	76.5	(71.2-81.8)	23.5	(18.2-28.8)
About right	79.2	(75.9-82.5)	20.8	(17.5-24.1)
Overweight	70.8	(60.8-80.8)	29.2	(19.2-39.2)
Obese	81.5	(73.9-89.1)	18.5	(10.9-26.1)
Time of Recognition of Pregnancy				
1-4 weeks	80.2	(75.9-84.5)	19.8	(15.5-24.1)
5-8 weeks	79.4	(75.9-82.9)	20.6	(17.1-24.1)
9-13 weeks	73.6	(66.3-80.9)	26.4	(19.1-33.7)
≥14 weeks	66.5	(54.3-78.6)	33.5	(21.3-45.7)
Prenatal Care Entry				
1st Trimester	79.7	(77.0-82.4)	20.3	(17.6-23.0)
Late or no care	72.3	(66.4-78.2)	27.7	(21.8-33.6)
Adequacy of Prenatal Care*				
Adequate	80.3	(77.4-83.2)	19.7	(16.8-22.6)
Intermediate	76.0	(69.3-82.7)	24.0	(17.3-30.7)
Inadequate	74.1	(66.7-81.5)	25.9	(18.5-33.3)
PNC Location				
Hospital Clinic	79.0	(72.5-85.5)	21.0	(14.5-27.5)
Health Dept.	63.3	(52.1-74.5)	36.7	(25.5-47.9)
Private M.D./HMO	79.2	(76.1-82.3)	20.8	(17.7-23.9)
Indian Health	78.4	(69.6-87.2)	21.6	(12.8-30.4)
Military/others	83.5	(75.7-91.3)	16.5	(8.7-24.3)
Method of PNC Payment				
Cash only	75.4	(68.3-82.5)	24.6	(17.5-31.7)
Priv/group insur	85.4	(82.5-88.3)	14.6	(11.7-17.5)
Indian Health	78.5	(70.3-86.7)	21.5	(13.3-29.7)
Medicaid	63.2	(56.1-70.3)	36.8	(29.7-43.9)
Free	68.7	(53.6-83.8)	31.3	(16.2-46.4)
Others	54.8	(32.5-77.1)	45.2	(22.9-67.5)

*Based on the Adequacy of Prenatal Care Utilization (APCU) Index.

ask them if they smoked prior to pregnancy, yet 12.8% of smokers indicated that their provider did not discuss with them the ways in which smoking during pregnancy could affect their baby. Two-thirds of nonsmoking women stated that their provider discussed with them the adverse effects of smoking during pregnancy.

Comment

LBW is a principal cause of high neonatal and infant mortality rates, numerous health and developmental problems in childhood, and major economic burdens, including the costs incurred for the hospital-based intensive care often required by infants who are born too small and too soon.[8] The results of this study showed that the mean birth weight of infants born to smokers was 255 grams less than that of infants born to nonsmokers. In addition, smokers were more than twice as likely to deliver LBW infants as nonsmokers. These findings are consistent with previous studies which have reported, with variations between studies, that the mean birth weight of infants born to smokers is approximately 200 grams less than that of infants born to nonsmokers and that the LBW rate of smokers is approximately twice that of nonsmokers.[9-14] In addition, prenatal smoking was found to be widely prevalent among women in Oklahoma with more than 1 in 5 women in the study reporting cigarette smoking during the last three months of pregnancy. Nationally, 21% of pregnant women smoke, according to the Behavioral Risk Factor Surveillance System for 1985-1986.[4]

Data from a 1986 Linked Telephone Survey that reinterviewed white women, aged 20 to 44, who were respondents to the National Health Interview Survey (NHIS) revealed that younger women, women with 12 or fewer years of formal education, and the unmarried were the groups least likely to quit smoking during pregnancy.[15] PRAMS data included a sample of all women who had recently given birth, and women in Oklahoma reflected these trends (Table 4).

Prenatal smoking cessation has the potential for dramatically reducing preventable adverse outcomes in pregnancy. Physicians can make a difference in smoking behavior among their patients. Women who receive strong stop-smoking messages from their physicians are more likely to quit than those who do not.[16] While a majority of prenatal smokers in this study reported that their provider discussed with them possible effects of smoking during pregnancy, it is not clear what specific provider methods were used to counsel women. Further research is needed to determine effective methods of promoting smoking cessation, and maintaining abstinence throughout pregnancy, as well as after delivery.

The prevalence of maternal smoking points out the need for physicians, in both public and private settings, to routinely educate their clients about the effects of smoking

Table 4. Smoking Prevalence Rates During the Three Months Prior to Pregnancy and During the Last Three Months of Pregnancy by Maternal Demographic Characteristics

Characteristics	3 Months Before Pregnancy %	(95% CI)	Last 3 Months of Pregnancy %	(95% CI)
Age				
Under 20	47.2	(38.4-56.0)	27.1	(19.3-34.9)
20-24	36.0	(30.7-41.3)	23.6	(18.9-28.3)
25-29	27.5	(23.0-32.0)	19.7	(15.6-23.8)
30-34	25.9	(20.0-31.8)	20.7	(15.0-26.4)
35 and up	23.9	(13.5-34.3)	14.7	(6.1-23.3)
Education*				
Under 12 years	54.7	(48.5-63.3)	35.5	(28.4-42.6)
12 years	35.4	(31.1-39.7)	26.3	(22.9-30.7)
13-15 years	22.1	(16.6-27.6)	12.7	(8.4-17.0)
16 years and up	8.2	(4.5-11.9)	5.4	(2.1- 8.7)
Race				
White	33.3	(30.2-36.4)	23.5	(20.8-26.2)
Black	14.0	(7.1-20.9)	9.2	(4.3-14.1)
American Indian	41.4	(31.6-51.2)	21.0	(13.2-28.8)
Other	2.2	(0.04-4.4)	0.2	(0.004-0.4)
Marital Status				
Married	26.4	(23.7-29.1)	18.5	(16.1-21.9)
Unmarried	55.0	(47.4-62.6)	35.2	(27.8-42.6)

*Excludes mothers under age 19.

Table 5. Provider Discussion of Smoking During Prenatal Care by Women's Smoking Status During the Last Three Months of Pregnancy

Status	Asked	(95% CI)	Discussed	(95% CI)
Nonsmoker	93.9	(92.3-95.5)	64.6	(61.5-67.7)
Smoker	95.3	(92.8-97.8)	87.2	(82.9-91.5)
Total	94.2	(92.8-95.6)	69.6	(66.9-72.3)

on the woman and the fetus, and support her efforts to quit. Considering the high smoking prevalence rates among health department clients and women whose prenatal care is funded by Medicaid (in public and private settings), the potential for positively influencing both public and private service delivery systems is great. We would argue that the net costs for such programs would be small compared to potential long-term expense for neonatal intensive care unit (NICU) care or other medical interventions. Prenatal smoking cessation education is a cost-effective method of reducing adverse outcomes. For every $1 spent on education, $3.31 is saved in NICU costs alone.[17]

One of the best ways to prevent adverse birth outcomes associated with smoking is to prevent the initiation of smoking among girls and young women. Our findings suggest that particular attention needs to be paid to those who are young and to those with less formal education since the prevalence of smoking was highest for these groups. Interventions that include coping skills, encouragement to remain tobacco-free, and role models who do not use tobacco may be of benefit. Physicians have the potential for making a positive statement to young people and would serve their communities well to exercise every power they have to promote a tobacco-free generation of mothers and children through patient education and support of legislation to control the use of tobacco products.

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Acknowledgments

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From the Centers for Disease Control and Prevention: Ms. Bruce is an epidemiologist in the Pregnancy and Infant Health Branch, Division of Reproductive Health.

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News

Tom Peace takes over as state's commissioner of health

Thomas D. Peace, PhD, has been Oklahoma's state commissioner of health since February 1. Dr. Peace, formerly assistant commissioner and then deputy commissioner of health, was appointed to his post by the Oklahoma State Department of Health (OSDH). He succeeds Joan K. Leavitt, MD, who announced her retirement earlier in the year.

Dr. Peace began his career as a public health advisor to the U.S. Department of Health, Education, and Welfare in 1965. After obtaining his first master's degree in public administration in 1970, he worked as a research associate in the Dean's office at the University of Oklahoma College of Public Health. In 1972 he completed a second master's degree, in environmental health.

A year later, having completed his doctorate in public health, he began four years as adjunct assistant professor and assistant professor in the OU Department of Human Ecology and Environmental Health. He also served as director of the Department of Pollution Control from 1973 to 1975 and worked for two years as executive vice president of the Oklahoma Frontiers of Science Foundation. In 1978 Dr. Peace became adjunct assistant professor in the OU Department of Family Practice and Community Medicine. He joined OSDH in 1981.

AMA managed care seminars debut next month in Chicago

The American Medical Association (AMA) has launched a comprehensive initiative to assist AMA members to understand, adapt to, and prosper in the managed care environment. A primary goal of the initiative is education of AMA members through written materials and seminars that will be conducted around the country.

The AMA will showcase its first managed care seminar on June 11 at the annual meeting of the Hospital Medical Staff Section (HMSS), which precedes the AMA's annual meeting in Chicago. This program will accompany two other HMSS educational programs: Negotiations and Conflict Resolution and a Review and Analysis of President Clinton's Health Care Reform Plan.

Worth Repeating

GAO's January report criticizes national data bank management

The following memorandum was originally distributed by the American Medical Association (AMA) Health Law Division in the April 1993 Medical Staff Legal Advisor. *It summarizes a January 1993 report of the United States General Accounting Office (GAO) entitled* Health Information Systems: National Practitioner Data Bank Continues to Experience Problems *(GAO/IMTEC-31-1).*

GAO's Summary of HHS Shortcomings

As with a previous report issued by the GAO in 1990 [*Information System: National Health Practitioner Data Bank Has Not Been Well Managed* (GAO/IMTEC-90-68)], the 1993 report is highly critical of the Department of Health and Human Services' (HHS) management of Data Bank operations. Three major shortcomings are cited.

■ **Responses by the Data Bank to queries are not timely, and security problems continue.**

• The Data Bank's responses to queries continue to be slow; users do not receive responses to queries for

(continued)

GAO report on data bank *(continued)*

several weeks, lessening the effectiveness of the information for decisions regarding health care practitioners.

• Response delays are due to reliance on paper documents for submitting queries rather than other methods such as telecommunications; the frequent absence of social security numbers on reports and queries; and software deficiencies that cause premature termination of processing.

• The process used for handling query responses does not provide necessary security for sensitive practitioner data; query responses were mailed to the wrong address in at least six cases due to insufficient internal controls.

• With regard to the issue of inadequate security, the GAO report noted that although the Health Care Quality Improvement Act of 1986 prohibits the release of specific information to unauthorized entities, the Data Bank lacks sufficient controls to ensure that responses containing sensitive data are mailed to the correct address. An average of 250 queries and other correspondence are returned to the Data Bank each month as a result of improper mailing addresses. HHS cannot estimate the total number of cases in which sensitive data was sent to unauthorized parties, as documents mailed to the wrong address are not necessarily returned to the Data Bank.

• In addition, six cases were identified by the GAO in which user organizations advised the Data Bank that they had obtained practitioner data to which they were not entitled.

• The GAO report noted that other organizations that manage similar data, such as the American Medical Association (AMA) and the Federation of State Medical Boards, use greater care in releasing sensitive information on practitioners.

■ **HHS is not adequately monitoring the Data Bank's automated system.**

• The contractor has foregone correcting known system deficiencies because HHS has not monitored the contractor's operation of the automated system. Therefore, system processing deficiencies continue, system documentation is inaccurate, and proposed changes have not been thoroughly reviewed.

• Although HHS officials contended that monitoring of the system was limited due to insufficient resources, the agency in fact had funds available for this purpose that were not used.

■ **HHS has not adequately planned for the future direction and financing of the system.**

• HHS's plans to redesign the current inefficient automated system are flawed; the timing and sequence of development tasks have not adhered to generally accepted system development principles, and user needs have not been adequately considered.

• HHS's plans are based on uncertain funding. As

In Memoriam

1992	
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Don Horatio O'Donoghue, MD	April 20
Billie Gene Henley, MD	April 24
Arlo Kenneth Cox, MD	April 27
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Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
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Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28
1993	
Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Edward Cotter Murray, MD	April 9

Opinions abound at health care reform summit in D.C.

On March 24 and 25, some 1,000 American Medical Association leaders and physicians from across the country met in Washington, D.C., with federal health care policymakers to discuss health care reform. Among those attending was Timothy B. Norbeck, executive director of the Connecticut State Medical Society. Norbeck compiled and distributed several pages of quotations from the two-day event, and included some of observations of his own.

The quotes make interesting reading, particularly with the details of the Clinton reform plan scheduled to be released this month:

■ **Senator Don Nickles (R-OK), Senate Appropriations Committee—** "When we make changes in our health care system, we must make sure that we do no harm and that we improve it, not damage it further."

"We must preserve quality."

"Price controls would be disastrous."

"We cannot impose an expensive new health benefits package on business."

"We need more competition in our system and must give people options... Cannot limit consumer choice."

■ **Representative Pete Stark (D-CA), Chairman, House Ways and Means Subcommittee on Health—** "There is no place where an HPPC (Health Plan Purchasing Coalition) exists."

"With managed competition, there will be more and more hassles and the end of independent practitioners."

"We cannot do this (reform) without you physicians."

"We cannot have a new system where my mother can't go to her doctor."

(continued)

GAO report on data bank *(continued)*

HHS does not have authority to pay for development of an improved system with user fees, HHS may need to delay rewarding a contract for such a system until it obtains authority to pay to do so.

GAO Recommendations

The GAO recommended that the Secretary of HHS direct the Administrator of the Health Resources and Services Administration to:

- Establish a user fee policy that will encourage electronic querying;
- Send information to reporting and querying entities that encourages the use of social security numbers;
- Institute additional safeguards to ensure that practitioner identification data on queries match reports and that responses to queries are mailed to the correct entity; and
- Use necessary technical expertise to perform routine on-site monitoring of the contractor's operation of the automated system.

The GAO further recommended that the Secretary of HHS:

- Direct the Deputy Assistant Secretary of the Office of Information Resources Management, responsible for ensuring consistency with information resources management requirements, to provide independent technical oversight for development of the new automated system.
- Delay the award of a contract for development of a new automated system until user needs have been adequately identified, requirements have been fully defined, and alternatives have been assessed.
- Immediately pursue funding authority for development of the new system.

HHS's Response

HHS agreed, for the most part, with the GAO's recommendations, and stated that it had already initiated some corrections.

Regarding the GAO's recommendation that social security numbers be used, HHS noted that it had sent a proposal to Congress to provide for mandatory reporting of social security numbers, but that Congress had taken no action on the proposal. The GAO continues "to believe that HHS should proceed with the steps it was considering to encourage organizations to supply SSNs on reports and queries."

The AMA has argued strongly against the use of social security numbers either as a mandatory data element or as a Data Bank identification number. Social security numbers are too easily accessible by other parties. It is the AMA's position that the Data Bank would be better served by the use of a more secure identification number that is controlled by the contractor.

—Ilene Davidson Johnson, JD
American Medical Association
Department of Professional Liability and Insurance

Health care reform *(continued)*

Note: Mr. Stark is a critic of managed competition and favors the Canadian single payor mode.

■ **Phil Gramm (R-TX), Senate Appropriations Committee—** "I'm trying to do the Lord's work in the Devil's city."

"If one works and has health care coverage through an employer, unless we are very careful, after reform he or she will pay more for less."

"Either they don't know what they are talking about [regarding managed competition and global budgeting] or they don't want me to know what they are talking about... Nobody has the foggiest idea what it means... It sounds like a great system that will work great until someone gets sick."

"Global budgeting means rationing of care."

"Price controls haven't worked in 5,000 years."

"Sin taxes won't pay for 5% of the new health plan; there will have to be new taxes."

"We need tort reform. If one sues and fails in that effort, the person should be liable for costs."

"Clinton's health care package is not a done deal. It's a long way from being adopted."

■ **Edward M. Kennedy (D-MA), Chairman, Senate Labor and Human Resources Committee—**"Reform must build on the great strengths in our health care system and repair what is not working."

"You physicians must be involved in reforming the system and making it work."

"No groups's cooperation is more important if costs are to be saved."

"Medical decision making belongs in the skilled hands of our nation's physicians."

"No group has more at stake and no group has more to contribute."

"We cannot expect physicians to police their own when there are antitrust barriers."

■ **Albert Gore, Jr., Vice-President of the United States—** "Physicians must be a very big part of the solution because this crisis strikes at the heart of every American family."

"It's not right that physicians have to practice with government looking over their shoulder."

(continued)

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Health Department

Trichloroethylene toxicity poses a danger in Oklahoma

The Oklahoma State Department of Health and the U.S. Agency for Toxic Substances and Disease Registry are working cooperatively to increase health professionals' awareness of hazardous substances in the environment and to provide them with the necessary information to recognize and evaluate potentially exposed patients.

Trichloroethylene (TCE) has been identified at three of the ten National Priorities List sites designated in Oklahoma for Superfund cleanup, in addition to many state-identified hazardous waste sites. TCE is a man-made chemical that does not occur naturally in the environment. It is mainly used as a solvent and as a building block to make other chemicals. TCE is a colorless liquid at room temperature and has an odor similar to ether or chloroform.

At hazardous waste sites, trichloroethylene is released to the air by evaporation and to underground water when it passes through the soil. Other environmental sources of TCE are evaporation to the atmosphere from work done to remove grease from metal and evaporation from adhesive glues, paints, coatings, and other chemicals. Many consumer products also contain TCE, such as typewriter correction fluids, paint removers and paint strippers, adhesive glues, spot removers, cleaning fluids for rugs, and metal cleaners.

The primary routes of exposure for trichloroethylene are inhalation and ingestion of contaminated water. TCE also can enter the body through dermal exposure. The U.S. Environmental Protection Agency (EPA) has established a drinking water standard of 5 parts per billion parts of water (ppb). This applies to community water systems and those which serve 25 or more persons for at least 6 months. The EPA requires industry to report spills of 1,000 pounds or more of TCE; however, it has been proposed that this level be reduced to 100 pounds.

Physicians should note that inhalation of trichloroethylene may result in dizziness, headache, fatigue, slowed reaction time, sleepiness, and facial numbness. Ingestion may also result in these effects. Irritation of the eyes, nose, and throat can occur under these conditions as well. Concurrent alcohol consumption and TCE exposure can result in "degreaser's flush," a temporary redness and itching of the back, neck, and face. More severe effects on the central nervous system, such as unconsciousness and possibly death, can occur from drinking or breathing higher levels of TCE. In general, the less severe central nervous system effects that result from one or several exposures to trichloroethylene disappear when exposure ends.

Long-term exposure to trichloroethylene may result in persistent health effects. Based largely on animal studies, research has shown that long-term exposure to high levels of TCE can produce nervous system changes; liver and kidney damage; effects on the blood; tumors of the liver, kidney, lung, and male sex organs; and possibly leukemia. Results of a few studies in pregnant animals indicate effects on the unborn or newborns. Prolonged contact to TCE may also result in contact dermatitis, rashes, and burns.

Recent or ongoing exposures to trichloroethylene can be determined by measuring TCE in the breath. Another way of determining whether exposure has occurred is by measuring a number of metabolites of TCE, such as trichloroacetic acid, in the urine or blood. The presence of TCE metabolites should be interpreted with caution because medications, such as chloral hydrate and disulfiram, and other chlorinated hydrocarbons are also metabolized to trichloroacetic acid. Removal from the source and supportive care is the recommended treatment for acute TCE exposure. Potentially involved organ systems should be independently evaluated and supportive measures initiated.

Health care reform *(continued)*

"We (Clinton Administration) will try very hard to reform malpractice laws and cut down on administrative paper work hassles."

"The days when one association, no matter how prestigious, can dominate the health reform debate, are over. And they should be."

"We will preserve the patient's right to choose the physicians they want and they will be able to choose the coverage they want."

"We need malpractice reform... Too often people sue doctors when doctors haven't done anything wrong."

"The doctor, patient and accountant—the new triad of medicine."

"We must balance the American people's needs with yours."

(continued)

75 Years Ago

Comparing Annual Meeting with 1918 version proves interesting

Seventy-five years ago the Annual Meeting of the OSMA House of Delegates was held in Tulsa, as it was this year. Two months before that meeting, in March 1918, the Journal of the Oklahoma State Medical Association *issued the following editorial advice to members:*

The Tulsa Meeting

This meeting will be held May 14, 15 and 16. Physicians contemplating attendance are warned now to make reservations for the meeting at a very early date. Ten days or two weeks notice will not do at all, as is the case with most conventions, but the reservation must be made far in advance. Tulsa is the most crowded city in the United States, all hotels and rooming houses, as well as apartments, are crowded to the utmost at all times and the local physicians are suggesting this warning at an early date in order that attendants may provide for themselves in time or otherwise be left without any accommodations.

Following is a list of the better hotels, but in addition to that there are others, which are good, not here listed: Alexander Hotel, 219 S. Boston, $1.00 and up; Tulsa Hotel, $2.00 up; Ketchum Hotel, $2.00 up; Brady Hotel, $1.00 up; Lee, $1.00 up; Lahoma, $1.00 up; Majestic, $1.00 up; Marquette $2.00 up; Oxford, $1.00 up; Oklahoma, $1.50 up.

These are among the best in town. The Tulsa, Alexander, Ketchum, Marquette, Oklahoma and Brady are the best.

Report of the Secretary-Treasurer-Editor, May 1918

Receipts:

Balance April 30, 1917	$2,283.52	
Advertising	3,157.83	
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Time Deposits Surrendered	1,500.00	
Interest on Time Deposits	51.34	
County Secretaries	4,505.58	$11,774.27

Expenditures:

Telephone, telegraph, express	$ 13.72
Office Supplies	116.30
Postage	198.00
Printing Journal, extras, etc.	3,296.82
Stenographic and Clerical Work	412.70
Reporting Meetings	140.13

Health care reform *(continued)*

■ **Robert Dole (R-KS), Senate Minority Leader—** "We must approach the issue of health care reform on a bipartisan or nonpartisan basis."

Mr. Dole complained that "Hillary Rodham Clinton met with 35 Republican Senators ten days ago, and we have been told in effect that they don't want Republican input on health care."

"We must preserve the high quality of care."

Mr. Dole listed six items as principles of a health plan he could support: (1) protect quality; (2) preserve freedom of choice; (3) preserve jobs; (4) no government controlled care ("We are not Sweden or Germany. We are different, and we need an American solution."); (5) control costs, not care—global budgeting and price controls will reduce quality of care and will target symptoms, not the cause; and (6) tort reform ("Democrats should stand up to the trial lawyers)."

"When we are sick, we consult with our doctor. Why not now?" This comment elicited perhaps the most applause of the day (said in reference to the working groups on health reform)

"We should market test health reform before imposing it on the entire country."

"After May 3 when the Clinton reform proposal is presented, there will be many hearings and debates... I don't want artificial deadlines."

■ **George Mitchell (D-ME), Senate Majority Leader—** "Your input will be very helpful."

"Physicians are drowning in paperwork."

"Malpractice needs reform."

"We must imprint on the mind of the patient that he or she is paying for the service... Massive education is needed to show people that someone is paying for that care."

"If one can defer paying for something (he used the example of credit cards), it is normal to expect that more goods and services will be purchased and

(continued)

Chiropractic Expense	1,737.54	
Refund County Secretaries	4.50	
Councilors, Delegates and Committee Expense	466.17	
Secretary's Salary	900.00	
Press Clippings	27.00	
Treasurer's Bond	10.00	
Auditing Books	10.00	
Transfer, Medical Defense Fund	1,375.00	
Certificate of Deposit, Com. Natl. Bank	500.00	
Liberty Bond	500.00	$9,697.88
May 1, 1918, Balance		
Cash on Hand	$2,076.39	
Certificate of Deposit	1,000.00	
Liberty Bond	500.00	
Total Cash Resources Medical Assn	$3,576.39	

Medical Defense Fund Receipts

May 1, 1917, Balance on hand in Bank	$503.00	
April 30, 1918, Oklahoma State Medical Assn	1,375.00	
April 30, 1918, Interest, Time Deposit	100.00	$1,978.00

Expenditures

July 17, 1917, Attorneys' Fees	$300.00	
September 22, 1917, Attorneys' Fees	50.45	
April 17, 1918, Attorneys' Fees	50.00	
April 30, 1918, Time Deposit, Com. Nat'l Bank	1,000.00	$1,400.45
May 1, 1918, Balance Cash in Bank	577.55	
Time Deposit, Commercial National Bank	3,000.00	
Total Cash Resources, May 1, 1918	$3,577.55	
Total Cash Resources All Funds	$7,153.94	

Respectfully submitted,
C.A. Thompson, Secy-Treas.

[*Note: Association membership on April 30, 1918, totaled 1,386.*]

Reprinted from *J Okla State Med Assoc*, June 1918.

Health care reform *(continued)*

demand will increase... imagine the demand when people think it's free."

■ **Donna E. Shalala, PhD, Secretary of Health and Human Services—** Cited the following in a discussion of health care costs:

—21% of heart disease is attributable to smoking

—87% of lung cancer is caused by smoking

—40% of drownings are related to alcohol use, as are 50% of motor vehicle deaths

—12 million Americans get sexually transmitted diseases each year, of which 8 million are under the age of 25

—preschool immunization rate is under 60%

"We need a uniform level of care for all children."

"We are committed to treating the causes of illness rather than just the illness itself."

■ **Newt Gingrich (R-GA), House Minority Whip—** "The American people deserve to have an open opportunity to know the identity of those in the work groups who are discussing how 14% of the GNP will be spent."

"To be told you will have a global budget without rationing is intellectually dishonest."

"If you could see the number of lawyers in the work groups, you would see what kind of tort reform you will get."

"If the American people understood the Clinton health plan, it would die of its own weight... That is why the Administration is trying to rush it through Congress so fast."

"Physicians should ask their congressional representatives to promise a fair discussion of the Clinton health plan this summer so that the people really understand what is at stake."

■ **John D. Rockefeller IV (D-WV), Chairman, Senate Finance Subcommittee on Medicare and Long Term Care—** "Pressure from business and labor is overwhelming for comprehensive health care reform."

(continued)

Health care reform *(continued)*

"You add the Clinton and Perot votes together (62%) to get the way the American people feel about change."

"Comprehensive reform won't happen if it doesn't happen this year, because the momentum will be lost."

"Failure to act now can have only two results: it will build pressure for a single payor system which has some support in Congress or we will see a slow, continuing collapse of the system, growing paperwork and more uninsured."

■ **John Clowe, MD, AMA President—** "People accuse physicians of being a special interest group in the negative sense, as if those special interests are contrary to those of the country. We are a special interest group, and our special interest is our patients."

"Congress cannot cure our system without input from Medicine."

"Price controls treat symptoms, not the cause. How do you tell a cancer patient that price controls do not allow a treatment that both physician and patient know will be helpful and could save a life?"

"Physicians cannot presently negotiate with government when it comes to reimbursement. We need the freedom from antitrust regulations."

"Patients must retain the freedom to choose their own physicians, and physicians must be free to choose the practice of their choice."

"President Clinton mentioned 64 days ago that there is nothing wrong with America that can't be fixed by what is right about America. The same holds true for our health care system."

■ **Ray Scalettar, MD, Chairman of the AMA Board of Trustees—** "We don't have global patients; we treat our patients one at a time."

"If our (physicians') position on health reform falls on deaf ears, then we will be members of the loyal opposition and represent our patients to the very best of our abilities... regardless of the risk."

■ **James S. Todd, MD, AMA Executive Vice-President—** "We have not bought into managed competition as it has been debated thus far in Washington. We have not embraced managed competition, lock, stock, and barrel."

"If the managed care competition approach offered on May 3 ends up with restrictions on patients and physicians, AMA won't sign it."

■ **Near the end of his report, Norbeck said:** "In football parlance, we are now is the 1st quarter. House committee hearings and debates will constitute the 2nd quarter. The 3rd quarter will involve Senate committee hearings and debates. Then the 4th quarter will center around the House and Senate conference committees. The best bet at this time is that despite President Clinton's desire for a very speedy process, it is unlikely that a full comprehensive bill will pass this year. Incremental changes might occur in 1993, but probably not the big one. AMA is still hopeful that the May 3 package from the Administration's Task Force will be positive. I would characterize as very skeptical, however, the feelings expressed by those in the audience as to the health reform package expected in early May."

Deaths

William Finis Ewing, Jr., MD
1927 - 1993

Tulsa Life Member William F. Ewing, MD, died March 31, 1993. A native of Washington, Okla., the retired physician served in the U.S. Army in 1946 and 1947. He was graduated from the University of Oklahoma School of Medicine in 1953. After completing an internship in Salt Lake City and residency training in Oklahoma City, Dr. Ewing established an internal medicine practice in Tulsa in 1958.

Willie George Long, MD
1924 - 1993

W. George Long, MD, Purcell, MD, died March 22, 1993. Born in Pauls Valley, Dr. Long enlisted in the U.S. Navy in 1943, serving 14 months in Okinawa, Japan. He was discharged with the rank of chief pharmacist mate. In 1952 he was graduated from the University of Oklahoma School of Medicine and in 1953 he moved to Purcell to work at McCurdy Hospital. Dr. Long continued his general practice in Purcell until his retirement in July 1989.

(continued)

John Robert McInnis, MD
1908 - 1993

John R. McInnis, MD, Oklahoma City, died March 31, 1993. Born in West End, North Carolina, Dr. McInnis was a 1956 graduate of the University of Tennessee College of Medicine. He served in the U.S. Army during World War II and retired with the rank of colonel in the Medical Corps Reserve. A general practitioner and surgeon, he practiced in Oklahoma City from 1956 until his retirement in 1988. Dr. McInnis was a Life Member of the OSMA.

Edward Cotter Murray, MD
1903 - 1993

E. Cotter Murray, MD, a retired general practitioner who specialized in aviation medicine, died April 9, 1993. Dr. Murray was born in Marceline, Mo., and attended the University of Oklahoma School of Medicine, where he was graduated in 1930. He returned to Missouri for his internship and established his first practice in Galletin, Mo. In 1939, after serving in the military for two years and the Civilian Conservation Corps for six years, Dr. Murray moved his practice to Ada, Okla. In 1954, Dr. Murray relocated his practice to Oklahoma City.

Waldo B. Newell, Jr., MD
1913 - 1993

OSMA Life Member Waldo B. Newell, Jr., MD, Enid, died Febraury 16, 1993. He was born in Hunter, Okla. A retired general practice physician, Dr. Newell was graduated from the Vanderbilt University School of Medicine in 1937. During World War II he served 41 months on active duty and held the rank of major when discharged. Dr. Newell practiced in Enid for more than 30 years prior to his retirement in 1968. Among his many professional activities was a term as president of the Garfield County Medical Society.

William Alfred Waters, MD
1912 - 1993

Longtime Tulsa physican William A. Waters, MD, died March 19, 1993. A native of Offerle, Kans., he earned his medical degree from the University of Oklahoma School of Medicine in 1947. He served on active duty with the U.S. Army during World War II, attaining the rank of first lieutenant. In 1954 he moved to Tulsa from Lubbock, Tex., and established a general practice. He was made a Life Member of the OSMA in 1982.

Homer Clark Wheeler, MD
1912 - 1993

Homer C. Wheeler, MD, a native of Sallisaw and a 1938 graduate of the University of Oklahoma School of Medicine, died February 18, 1993. He was a general practitioner at the McAlester Clinic for 35 years before his retirement. Dr. Wheeler was a World War II veteran, having served in the U.S. Army from 1942 to 1945. He earned several decorations for his service in the South Pacific and attained the rank of captain prior to his discharge.

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(continued on next page)

Physicians Wanted *(continued)*

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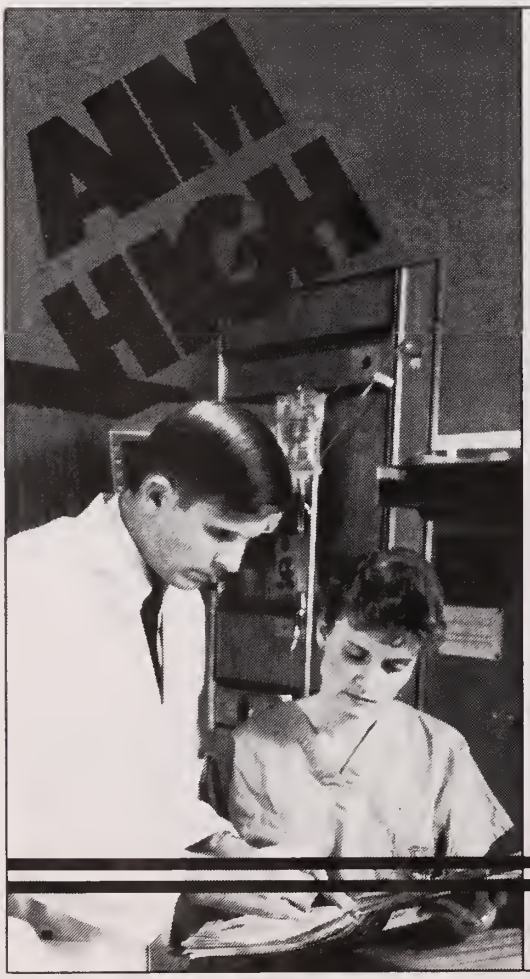
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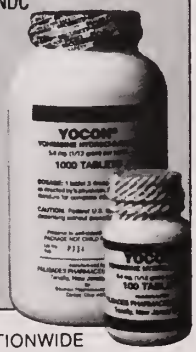
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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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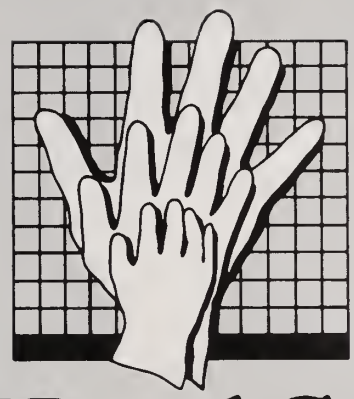
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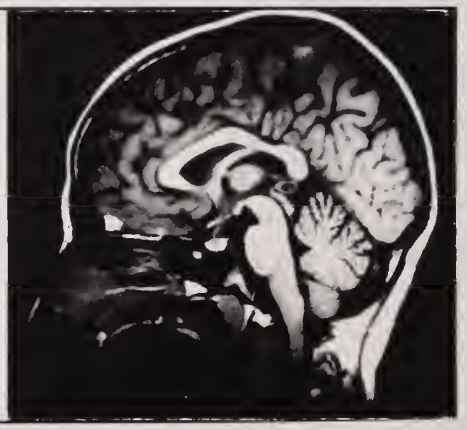
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THE LAST WORD

■ **The 21st Assembly Meeting of the AMA Hospi**tal Medical Staff Section will be held June 10-14, 1993, at the Chicago Marriott Hotel. With reform of the American health care delivery system dominating the news, three educational programs will be a part of the meeting: (1) Negotiations and Conflict Resolution; (2) Review and Analysis of President Clinton's Health Care Reform Plan; and (3) Challenge and Change in the Managed Care Environment. For more information, call (312) 464-4754 or 464-4761.

■ **"Update '93: Current Trends in Obstetrics and** Gynecology" is the title of a continuing education symposium for women's health care providers to be held Wednesday through Friday, May 19-21, at the Oklahoma City Marriott Hotel. The annual symposium is sponsored by the Department of Obstetrics and Gynecology at the University of Oklahoma Health Sciences Center; the American College of Obstetricians and Gynecologists, District VII, Oklahoma Section; the Oklahoma State Department of Health's Maternal and Child Health Service; and the Office of Continuing Medical Education at the OU college of Medicine. For more information, call the OU College of Medicine Office of Continuing Education, (405) 271-2350, or the OU Department of Obstetrics and gynecology, (405) 271-8717.

■ ***The Journal of the American Medical Association*** (March 24/31) reports that combination of the antihistamine terfenadine (e.g., Seldane) with the oral antifungal agent ketoconazole can cause a rare form of heart arrhythmia and possibly even fatal cardiac arrest. This reaffirms a 1990 report from the Food and Drug Administration (FDA) which warned of the dangerous drug interaction. Physicians have continued to prescribe the drugs in combination, and recently a 29-year-old woman suffered a fatal heart attack after taking both drugs, says the *JAMA* report. [Note: In the past, the FDA also has warned that the combination of terfenadine and the antibiotic erythromycin can cause heart rhythm problems.]

■ **Oklahoma City surgeon G. Rainey Williams,** MD, is the recipient of the 1993 Alexander Poston Leadership Award presented annually by the Oklahoma City Clinic. At an awards dinner and ceremony on April 3, Dr. Williams, the John A. Schilling professor and chair of the OU Department of Surgery, was honored for his achievements in medicine and his outstanding dedication and positive commitment to the community. A tireless contributor to Oklahoma medicine, Dr. Williams has in the past been named Stanton L. Young Master Teacher at the OU College of Medicine (1991), received the Edgar W. Young Lifetime Achievement Award from the College of Medicine student body (1989), been elected to The Johns Hopkins Society of Scholars (1991), and been inducted into the Oklahoma Hall of Fame (1986).

■ **The Tulsa County Medical Society Auxiliary** conferred Doctor of the Year honors on five Tulsa physicians during its annual Doctors Day dinner on March 7. Recognized for their many years of service to their community were Robert Jabour, MD; Melvin R. Swafford, MD; Jodie A. Stark, MD; Adolph N. Vammen, MD; and James E. White, MD.

■ **Ed L. Calhoon, MD, Beaver general practitioner,** has been elected president of the Oklahoma Heritage Association for 1993. Rod Frates, president of C.L. Frates and Company in Oklahoma City, was chosen as the annual presidential appointee to the association's board. Among those serving as directors for the association is Burt C. Montague, MD, Lawton obstetrician-gynecologist. The Oklahoma Heritage Association is a nonprofit organization dedicated to the preservation and recognition of Oklahoma's history and heritage.

■ **Rochelle E. Ablah, MD, Oklahoma City, recently** nominated as AMA Resident Physicians Section representative to the National Board of Medical Examiners, has been appointed to that post for a four-year term.

■ **America's best rural physician is being sought** for the new "Country Doctor of the Year" award. Nominations for the award will be accepted through July 1, 1993. The award recipient will receive a personalized plaque and will be provided with an interim physician for one week at no charge, a service normally valued at about $10,000. In addition, a bronze plaque bearing the honoree's name will be displayed in the Country Doctor Museum in Bailey, NC. The museum and an interim physician staffing service, Staff Care, based in Irving, Texas, are sponsoring the award competition. Nomination forms may be obtained by calling Staff Care (800) 685-2272 or the museum, (919) 235-4165.

PRAVACHOL® (Pravastatin Sodium Tablets)

CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Theretore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class ot drug, therapy should be discontinued and the patient apprised ot the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually tell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks tor the first three months, every eight weeks during the remainder of the first year, and penodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use ot pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no expenence with the use ot pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clotibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous tamilial hypercholesterolemia. In this group ot patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency: A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomenc metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12h}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 6 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects ot the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers ot patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Hardenan gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed ot the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticana, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, ano, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive: gynecomastia, loss ot libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemtibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses ot nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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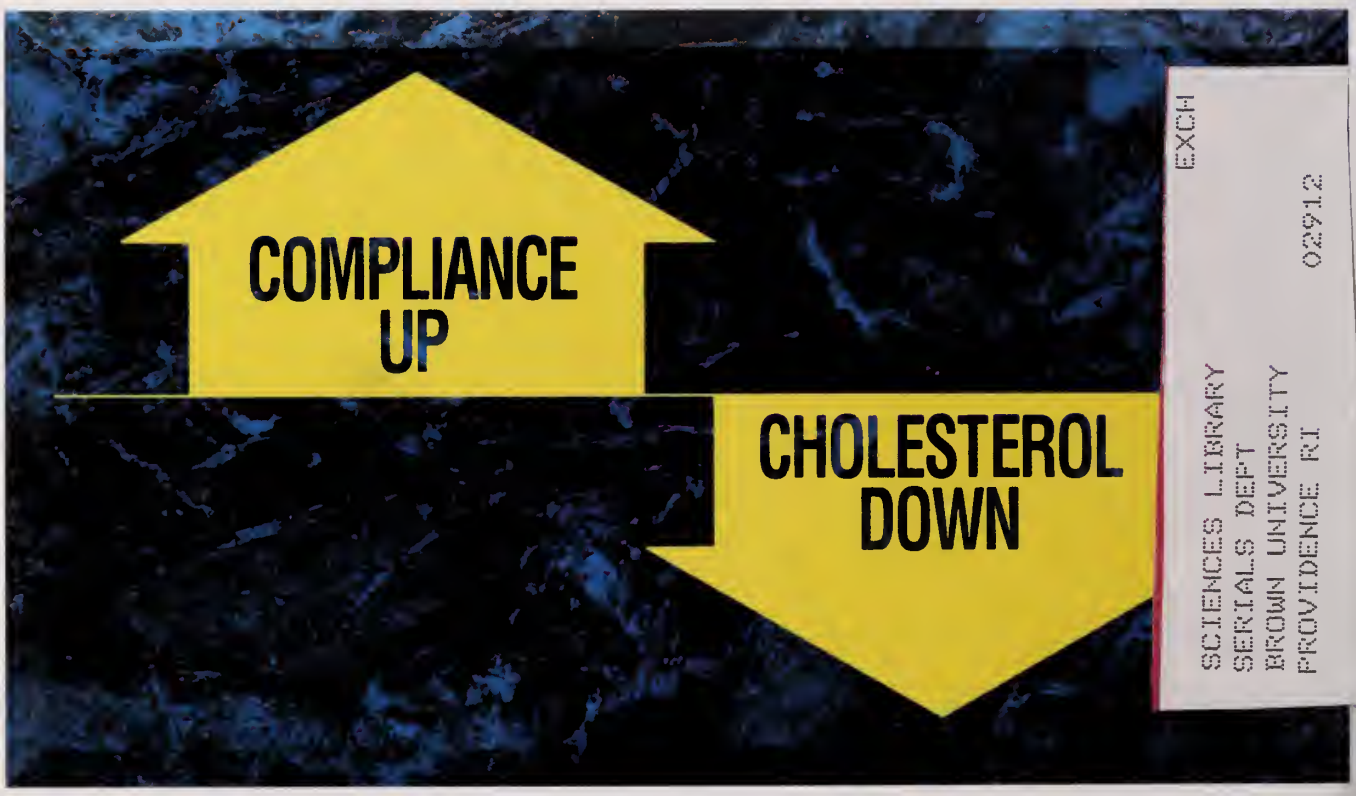
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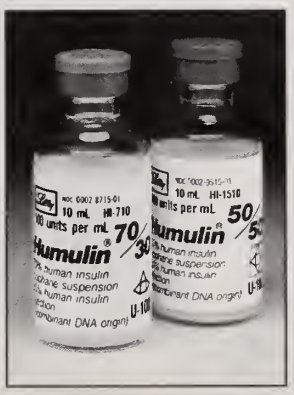
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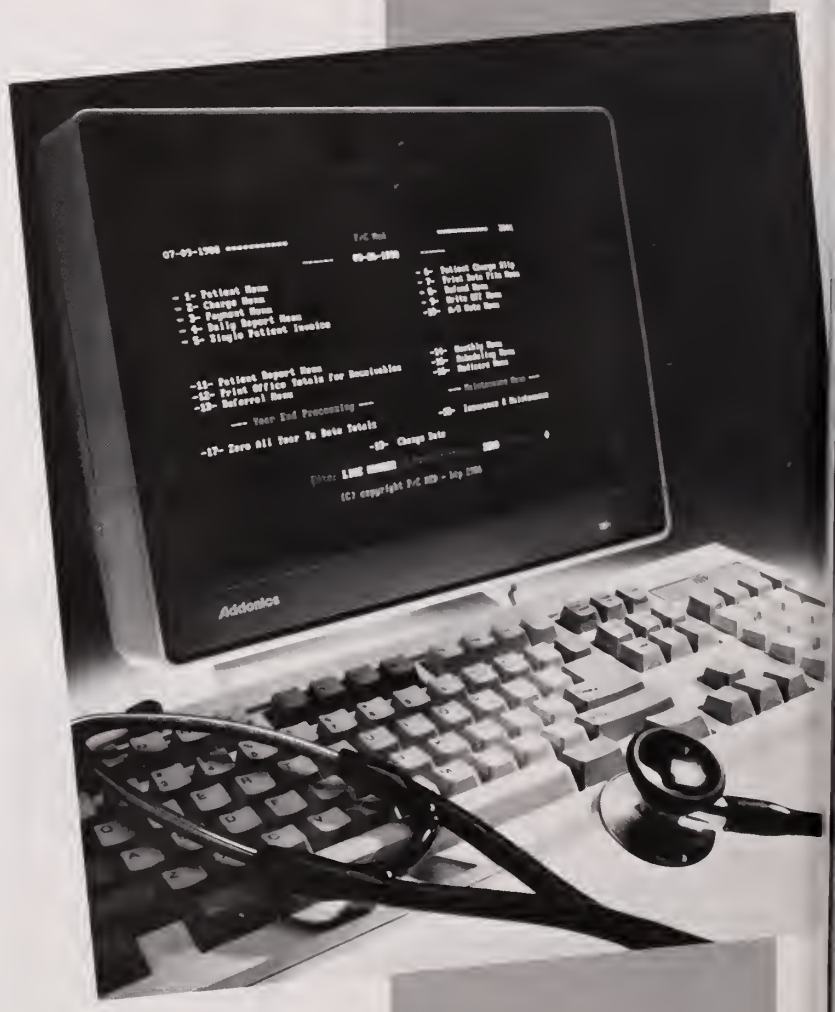
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Ray V. McIntyre, MD

The Timeless Tenet

In the current maze of physician/agency transactions, embranglements may generate the question: Is it ethical—or moral—for a physician to refuse to treat some particular class of patient, such as Medicaid, Medicare, homeless, diabetic, pregnant, dying, uninsured, etc?

Many such queries are rhetorical questions, and after the fact, but their presence implies a widespread notion that any licensed physician is a moral obligee to respond to every human complaint presented. However, universal acceptance has never been a traditional element of the patient/physician therapeutic contract. The possible exclusion of classes of patients has always existed and is clearly recorded in the ancient Egyptian medical papyri and the Babylonian code of Hammurabi. The Hippocratic Oath prohibited "cutting for the stone." Since antiquity, a discriminative intake procedure has been used by all patients and by most physicians.

In assessing the applicability of these ancient precepts to today's difficulties, we note that the patient/physician relationship remains very complex, and entails such responsibilities that—like marriage—it is not to be entered lightly. There are many variations in the natural course of human disease that the physician knows and considers before commitment. Does the patient have a life-threatening acute emergency within the scope and training of the physician? Are there probabilities of diseases or therapies outside the armamentarium of the physician? Is it to be a one-time, episodic, or permanent relationship? The physician must also judge if the patient can commit adequately to the therapeutic contract, including compliance, cooperation, instruction receptivity—and in the real world of today—paperwork and financial responsibility.

While the answers to these and many other possible questions are rarely known with absolute certainty, still the professional physician must expertly discriminate among the multiple motivations that impinge on the therapeutic contract. The guiding principle should be that the patient and the physician are of equal human rank in asserting both the positive and negative elements of these contrary human motivations. Both patient and physician must contribute something positive, and neither is dominant nor subservient.

Human patients have a natural right to refuse to go to a particular doctor, or to any doctor. The corollary for the physician, as a human being, is a right to refuse to treat a particular patient. A mature and responsible physician will never exercise the right of refusal in a manner that patient injury would result, but the right remains absolutely. The extension of this idea into the physician's right to refuse an entire class of patients morally requires the existence of a negative class effect on the therapeutic contract.

In today's patient population, there are many classes of patients that are the "captives" of government agencies and insurance programs. Government agencies are amoral and are solely controlled by political feasibility, and insurance companies have no compunctions outside of commercial feasibility. However, both of these entities may exploit physician altruism for political or commercial objectives, unhindered by ethical restrictions. Just as a good surgeon would be justified in refusing to operate in a stable, insisting on a less contaminated site as a condition of service, so we believe the ethical, moral physician may justifiably refuse to serve a class of patients where agency or insurance policies significantly contaminate the therapeutic alliance.

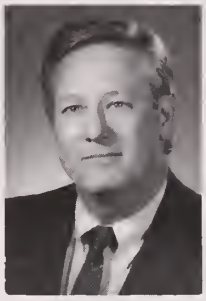
Most of the world's major religions and ethical systems contain a tenet that commands: "Do unto others as you would have them do unto you." The general use of this tenet would mitigate the quandary in most of the referral and therapeutic contract problems that arise in any age, including the Age of Medicare.

Ray V. McIntyre, M.D.

PRESIDENT'S PAGE

G. Lance Miller, MD

The Awakening



The end of April marked a significant happening for this association. I'm referring to the Annual Meeting of the House of Delegates, which in my opinion heralded a new and exciting chapter in the proud history of this organization.

There was a pervasive and exciting atmosphere of interest and anticipation that I have not seen in these meetings before.

For the first time, most of the elections for leadership positions were contested, and the debate both in the reference committees and on the floor of the house was much more intense. I was most pleased at the number of members who sought me out to volunteer for service this year, and be assured they will get their wishes.

I assume this escalation of interest is the result of an awakening to the perils for medicine which have been building for some time. Whatever the stimulus, I welcome this change, as it enhances my goal to bring as many members as possible into an active role in this association. Your leadership has embarked on many new programs, and we need the brain power that I know is lurking out there just waiting to be tapped. In hospitals, clinics, and private offices all over this state are physicians who have a great deal to offer to the collective house of medicine, but who, for many reasons I'm sure, just haven't seen fit to take that step of commitment.

I'm asking you now to consider taking that step.

There is room on every council and committee for you, and I know you have a lot to contribute.

If you perceive services that we as an organization can provide to you personally or to your county society, please make me aware of them.

And, to those of you who continue to wonder just what those jokers do at OSMA, I'm extending an invitation for you to attend a Board of Trustees meeting and observe us in action. The dates for those meetings are found on this page.* Just let us know in advance, and we will provide a chair for you.

On the legislative front, House Bill 1573 and Senate Bill 76 are, to date, the clear survivors of the numerous health care reform initiatives introduced at the beginning of the current session. It is our opinion that these bills will be reworked and combined in some fashion. Your leaders have "marked up" these bills, evaluating them literally sentence by sentence, and have advised the legislative leaders of the changes OSMA considers imperative if it is to support them.

By the time this writing appears in print, we will know just how effective our legislative efforts on this issue have been.

We have been assured that the sole intent of these bills is to provide a managed care system for Medicaid patients only. There is some sentiment for folding the state employees' PPO into this new system at a later date, if it proves to be functional.

From the opening bell in January, it has been crystal clear that both houses of the legislature were committed to the goal of revising (or reforming) the state's indigent medical care program, and many senators and representatives have made it clear to me personally that it was their intent to make it happen.

Thus, our efforts have been aimed at changing and sculpting the bill, especially to change wording that tended to broaden its scope beyond the sphere of Medicaid.

When will state government introduce total health care reform? Not this year, unless Governor Walters decides to call a special session on the issue.

Your association has decided that the governor's concept of health care reform should not be the only card laid on the table. Thus in early May I appointed a Health Care Reform Task Force whose charge is to develop a sensible and workable reform package, one that addresses the major issues of accessibility, affordability, and accountability, but does not place the major burden on providers.

I appreciate the willingness of these members to accept this responsibility, and I wish them God speed.

G Lance Miller, MD

*Board meetings have been scheduled for August 22, November 14, and February 20 in Oklahoma City, and April 14 at Shangri-La resort, Afton, Okla.

Symposium on Antimicrobial Therapy

IX. The Glycopeptide and Macrolide Antibiotics

Ronald A. Greenfield, MD

This is the ninth paper in Dr. Greenfield's continuing symposium on antimicrobial therapy, begun in the October 1992 JOURNAL.

IN this segment of this symposium we will discuss two families of antibiotics that have been available for over 30 years and have experienced a resurgence of interest and development in the past few years: the glycopeptide and macrolide antibiotics. These agents also perhaps share the similarity of activity primarily directed against Gram-positive bacteria, but as we will discuss, the newer macrolide antibiotics have interesting activity in addition to that against Gram-positive bacteria. We will begin with the glycopeptide antibiotics.

The Glycopeptide Antibiotics

The family of glycopeptide antibiotics currently has only one member approved for usage in the U.S., and that of course is vancomycin. It was originally discovered as a product of *Nocardia orientalis* (formerly *Streptomyces orientalis)* isolated from a soil sample from central Borneo in 1956.[1] Vancomycin is a 7-membered peptide chain consisting of two β-hydroxychlorotyrosine units, three substituted phenylglycine systems, N-methylleucine, and aspartic acid amide. It has a molecular weight of 1449 daltons and an empirical formula of $C_{66}H_{75}Cl_2N_9O_{24}$. Vancomycin gained approval by the U.S. Food and Drug Administration in 1958. It was used initially for treatment of penicillin-resistant staphylococcal infections. However, the release of methicillin in 1960 quickly reduced vancomycin usage; vancomycin was perceived as more toxic than the penicillinase-resistant penicillins and cephalosporins that were then rapidly introduced. Vancomycin usage, however, has surged in recent years, in response to the emergence of a number of Gram-positive bacterial pathogens susceptible principally only to vancomycin.

Vancomycin exerts its primary antibacterial effect by inhibiting cell wall synthesis in dividing organisms. This occurs at a different step in peptidoglycan synthesis than inhibition by β-lactam antibiotics; therefore cross-resistance does not occur. Vancomycin binds to the two terminal D-alanine residues when UDP-N-acetylmuramyl pentapeptide and N-acetylglucosamine are polymerized into peptidoglycan (second stage of cell wall synthesis). Secondary mechanisms of action involve a direct effect on the cytoplasmic membrane and inhibition of RNA synthesis.[2] Perhaps it is these multiple mechanisms of action that have enabled vancomycin to be useful for so long with as little development of resistance.[3] The antibacterial effect of vancomycin is usually bactericidal. However, most enterococci and some staphylococci are tolerant to the lethal effect of vancomycin (much higher concentrations required for killing than for inhibition).

From the Infectious Diseases Section, Department of Medicine, University of Oklahoma Health Sciences Center, and Medical Service, Department of Veterans Affairs Medical Center, Oklahoma City, Oklahoma.

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It is relatively easy to discuss the in vitro antimicrobial spectrum of activity of vancomycin. The in vitro activity is essentially limited to Gram-positive bacteria (some Neisseria are also susceptible). Among the Gram-positive bacteria, vancomycin is active against both cocci and bacilli, and active against both aerobic and anaerobic bacteria. Among Gram-positive bacteria, relatively few are only variably susceptible to vancomycin: Actinomyces, Lactobacillus, Leuconostoc, and Pediococcus species.[3,4] Within the past five years, vancomycin resistance has been clinically encountered in *Staphylococcus haemolyticus* (often considered to be *Staphylococcus epidermidis* group) and enterococci. There are three types of vancomycin resistance in enterococci.[5] VanA resistant strains have inducible high-level resistance to all glycopeptide antibiotics. VanA resistance is plasmid-mediated and transferable. VanB-resistant strains show inducible moderate-level resistance to vancomycin but are susceptible to some other glycopeptide antibiotics, including teicoplanin. VanC-resistant strains have constitutive resistance to vancomycin only. The presence of clinically encountered transferable resistance to glycopeptide antibiotics is a reason for substantial concern. Additionally, concomitant high-level vancomycin and penicillin resistance in enterococci has been encountered in clinical isolates.[6] The topic of enterococcal resistance to antimicrobial agents has been reviewed in this journal recently.[7]

Pharmacological properties of vancomycin are summarized as follows.[8] Vancomycin is essentially not absorbed after oral administration: there is *no* extraintestinal infection that can be treated effectively with oral vancomycin. However, orally administered vancomycin achieves high concentration in microbiologically active form in feces, a property used to therapeutic advantage. Intramuscular injection of vancomycin is painful and *never* recommended. Most patients should receive an initial vancomycin dose of 15 mg/kg total body weight.[9] In patients with normal renal function, intravenous administration of 1 gm of vancomycin q12h usually yields peak serum levels of 20 to 50 μg/ml and trough serum levels of 5 to 10 μg/ml. Vancomycin is cleared essentially entirely and unchanged by glomerular filtration. Dosage reduction is necessary in renal failure. Because creatinine clearance and vancomycin clearance are linearly related, the correct daily dose of vancomycin is approximated by 15 times the creatinine clearance (in ml/min); more complicated formulae and nomograms also exist. Because vancomycin pharmacodynamics resemble those of aminoglycosides, the daily dose, at least when reduced to less than 1 gm, can be administered once daily. Vancomycin is essentially not cleared by either hemodialysis or peritoneal dialysis. Functionally anephric patients require 15 mg/kg of vancomycin every five to nine days. Treatment of functionally anephric patients should be based on vancomycin serum levels: when the serum vancomycin level falls to <15 μg/gml, another dose should be given. Vancomycin should be infused over at least one hour to minimize occurrence of red man syndrome (described below). Vancomycin achieves therapeutic concentrations in most body spaces except the cerebrospinal fluid (CSF). Vancomycin does not achieve CSF concentrations that are reliable for the treatment of meningitis in adults.

There remains some controversy concerning the indications for monitoring vancomycin serum levels and individualizing dosing based on pharmacokinetic data. I believe much time, effort, and money are spent for little proven benefit. The problem focuses on lack of clear data that establish firm goals for peak and trough levels: specific levels associated with either efficacy or toxicity have not been determined.[10]

Although, as alluded to above, vancomycin is considered a fairly toxic antibiotic; progressive purification of the compound since its release in 1956 has resulted in a modern antibiotic with an acceptable profile of adverse reactions. The primary adverse effects associated with vancomycin use are ototoxicity and nephrotoxicity. Hearing loss may be reversible but is more likely permanent, and appears to be associated with prolonged serum levels >30 μg/ml.[3,11] Because hearing is not routinely monitored, an exact incidence of ototoxicity is difficult to determine. Nephrotoxicity has recently been reported to occur in 17% of patients treated with vancomycin.[12] Nephrotoxicity is usually mild and reversible.[12] Although the data are not unanimous, it is reasonable to presume that both ototoxicity and nephrotoxicity are more common when vancomycin is used in conjunction with an aminoglycoside.

Intravenous administration of vancomycin can be associated with an anaphylactoid reaction (caused by nonimmunological release of histamine) called the red man syndrome. This presents as a pruritic erythematous rash most prominent on the upper body, sometimes accompanied by fever and hypotension.[13] Chest pain and muscle spasm may also occur. Estimates of incidence in patients range from 2% to 90%, depending mainly on how closely the patient was monitored. This complication is reduced by infusion times ≥1 hour, and recurrence may be reduced by prophylactic hydroxyzine administration. Red man syndrome should rarely be a cause for discontinuation of therapy.

Other adverse effects associated with vancomycin therapy include infusion-related thrombophlebitis (13%), neutropenia (2%), drug-induced fever and rash (1-3%), and eosinophilia (rare).[3,14]

Therapeutic indications for vancomycin include serious staphylococcal or streptococcal infections in patients intolerant to the penicillins and cephalosporins or in patients infected with methicillin-resistant staphylococci or streptococci or enterococci resistant to β-lactam antibiotics. For treatment of serious infections with these organisms (such as infective endocarditis), vancomycin alone is adequate if the MBC <10 μg/ml; if it is not, additional agent(s) should be added. This rule applies to vancomycin treatment of enterococcal infections; for most enterococci the MBC is >10 μg/ml. Vancomycin is also indicated for treatment of infections due to other Gram-positive bacteria often resistant to β-lactam antibiotics, such as *Corynebacterium jeikeium* and *Rhodococcus equi.* Vancomycin may be substituted for penicillins and cephalosporins in prevention of surgical wound infections and in prophylaxis of infective endocarditis in patients with a history of hypersensitivity. Empiric use of vancomycin in the febrile neutropenic host has become popular, in view of the common occurrence of Gram-positive bacterial infections in this population.[15]

The single therapeutic indication for the oral preparation of vancomycin is for treatment of pseudomembranous enterocolitis due to *Clostridium difficile.* The recommended dosage is 125 mg PO q6h.[16] Metronidazole is also effective for treatment of *C. difficile* colitis and far less expensive. Although there has not been a direct comparison studied, many prefer to use vancomycin for more severe *C. difficile* colitis. Therapy is usually recommended for ten days.

As noted at the start of this segment, additional glycopeptide antibiotics are in development. One of these is teicoplanin. Teicoplanin has an antimicrobial spectrum of activity similar to vancomycin, but as noted above, some enterococci are sensitive to teicoplanin even when resistant to vancomycin. Teicoplanin also has some pharmacokinetic advantages over vancomycin: teicoplanin has a longer half-life that appears to enable once-daily dosing, it has greater lipid solubility enabling better tissue penetration, it can be given intramuscularly, and it may produce the red man syndrome less frequently than vancomycin.[3] However, recent reports of clinical failure of teicoplanin in treatment of staphylococcal infections have put further development of this agent in grave doubt.[17,18]

Just in passing, there are two other families of antimicrobial agents in development for potential future treatment of Gram-positive bacterial infections: a family of peptide antibiotics, represented first by mersacidin, and a family of peptolides, represented first by daptomycin. These agents are too far from potential clinical use to warrant further discussion here.

The Macrolide Antibiotics

The macrolide antibiotics are a family of antibiotics that structurally are a 14-, 15-, or 16-membered macrocyclic lactone ring to which generally two sugar moieties are attached. Macrolides presently available in the U.S. are erythromycin, clarithromycin (structurally 6-*O*-methyl-erythromycin), and azithromycin (structurally 9-deoxo-9a-aza-9a-methyl-9a-homoerythromycin). Azithromycin is often referred to as an azalide antibiotic, but it seems that this adds little but confusion. Spiramycin and josamycin are macrolides currently in use in Europe and Japan. A variety of other macrolides are in various stages of development.

The first macrolide, erythromycin of course, antedates its newer family members by over 30 years. Erythromycin was derived in 1952 from a product of *Streptomyces erythreus* recovered from soil in the Philippines. There are six products of erythromycin available for oral use: (1) enteric-coated tablets of erythromycin base (E-mycin® Ilotycin®, Ery-Tab®, Robimycin®, and generics); (2) enteric-coated pellets of erythromycin base in capsules (Eryc®); (3) film-coated tablets of erythromycin base (Filmtab®); (4) the stearate salt of erythromycin (Erythrocin®, Bristamycin®, others); (5) erythromycin ethylsuccinate ester available in tablet, chewable, and liquid forms (Eryped®, EES®, Pediamycin®); and finally (6) the lauryl sufate salt of the propionyl ester of erythromycin (erythromycin estolate) available in tablet, chewable, and capsule form (Ilosone®). Again, inclusion or exclusion of particular trade products does not imply presence or absence of this author's endorsement of particular trade products.

There are only two preparations of erythromycin for intravenous administration: erythromycin gluceptate and erythromycin lactobionate. Erythromycin can not be administered intramuscularly. Erythromycin is also available as 1.5% and 2% topical solutions for treatment of acne vulgaris and in an ophthalmic ointment for treatment of bacterial conjunctivitis and prevention of neonatal gonococcal and chlamydial ophthalmia neonatorum. These latter two preparations will not be discussed further. Finally, erythromycin is marketed in combination with sulfisoxazole: there is no indication for use of this combination in adults, so it will be discussed no further. This author lacks ade-

quate expertise to discuss the use of this antimicrobial combination in pediatric populations.

Erythromycin and other macrolide antibiotics exert their antibacterial action by inhibiting RNA-dependent protein synthesis at the stage of chain elongation.[19] Macrolides bind to the 50S ribosomal subunit, resulting in blockade of the transpeptidation and/or translocation reactions. Depending on drug concentration, bacterial density, bacterial growth stage, and the specific organism involved, the effect of macrolides may be either bactericidal or bacteriostatic.[19]

Several mechanisms of microbial resistance to macrolides have been described.[19] Resistance to the macrolides may be due to decreased permeability of the bacterial cell envelope to macrolide penetration. This is the general mechanism of resistance of the Enterobacteriaceae to macrolides. Furthermore, plasmid-mediated decreased permeability of erythromycin has been described in *Staphylococcus epidermidis.* High-level macrolide resistance can result from a single-step mutation involving a protein of the receptor site of the 50S ribosomal subunit. A third mechanism of macrolide resistance is alteration in the 23S ribosomal RNA of the 50S ribosomal subunit by methylation of adenine. This type of resistance is usually plasmid-mediated, is the result of at least three gene mutations, and is due to decreased binding of the antibiotics to their targets on the ribosome. It can be exhibited by strains of *Staphylococcus aureus,* streptococci (including *S. pneumoniae), Corynebacterium diphtheriae, Bacteroides fragilis, Clostridium perfringens, Listeria* species, and *Legionella* species. Finally, some Enterobacteriaceae possess a plasmid-mediated erythromycin esterase that hydrolyzes erythromycin to a microbiologically inactive form.

The in vitro antimicrobial activity of currently available macrolide antibiotics is summarized in Table 1.[20] Let us deal first with the antimicrobial spectrum of erythromycin; then we will discuss the newcomers. Erythromycin demonstrates a broad-spectrum of antimicrobial activity. It is active against certain Gram-positive and Gram-negative aerobic and anaerobic bacteria, mycoplasmas, chlamydiae, rickettsiae, treponemes, mycobacteria, and actinomycetes.[19] Most streptococci are susceptible to erythromycin, but some, including some pneumococci, are not. Approximately 70% to 80% of *S. aureus* isolates are susceptible to erythromycin, but the development of resistance by *S. aureus* during erythromycin therapy is not uncommon. Methicillin-resistant *S. aureus* are generally resistant to macrolides. Therefore, macrolide antibiotics should *not* be used for treatment of serious *S. aureus* infections. Enterococci are similarly variably sensitive to erythromycin and other macrolides, but again, serious enterococcal infections should *not* be treated with macrolides. Most strains of *Corynebacterium diphtheriae, Propionibacterium acnes, Peptococcus* and *Peptostreptococcus* species, and *Listeria monocytogenes* are susceptible to macrolides. Erythromycin has substantial in vitro activity against *Actinomyces israelii, Mycobacterium scrofulaceum, Mycobacterium kansasii,* and *Nocardia asteroides.*

Among Gram-negative bacteria, erythromycin has substantial activity against *Neisseria meningitidis, Neisseria gonorrheae, Bordetella pertussis,* and *Campylobacter* and *Helicobacter* species. Although erythromycin was once an alternative regimen for treatment of gonorrhea, multiple more effective regimens now exist. Most *Moraxella cattarhalis* isolates are susceptible to erythromycin. The activity of erythromycin against *Haemophilus influenzae* is variable. Erythromycin has some activity against Gram-negative anaerobic bacteria, but *Bacteroides fragilis* is frequently resistant.

Erythromycin also has clinically useful activity against *Treponema pallidum, Legionella pneumophila* and other legionellae, *Chlamydia trachomatis, Chlamydia pneumoniae, Chlamydia psittaci, Mycoplasma pneumoniae, Ureaplasma urealyticum,* some *Rickettsia* species, and *Rochalimea henselae.*

Now let's discuss the newcomers. Clarithromycin is more active than erythromycin against the streptococci, legionellae, and chlamydiae. It has greater activity against anaerobic bacteria than erythromycin. Perhaps the most interesting activity of clarithromycin is against *Mycobacterium avium intracellulare* complex organisms. Azithromycin is less active than erythromycin against Gram-positive bacteria, but more active than erythromycin against *Mycoplasma, Chlamydia, Haemophilus, Moraxella, Legionella,* and the gonococcus. The most interesting activity of azithromycin may be against the coccidial protozoans *Toxoplasma gondii* and *Cryptosporidium parvum.*

The pharmacokinetic properties of the macrolides are as follows.[19] Erythromycin base is subject to destruction by gastric acid. Therefore most modern preparations are formulated to delay dissolution. The esters and ester salts are more acid stable, and are absorbed and microbiologically active principally as the free base. All but the estolate are absorbed better in the fasting state; absorption of the estolate is unaffected by concomitant food intake. It may be that higher serum levels are obtained with the estolate than with other preparations. Erythromycin distributes well to tissues

(adequate CSF levels may be achieved with high dose intravenous therapy, but this is not well studied and is not recommended for any therapeutic indication) and persists in tissues longer than in serum. The serum half-life of erythromycin is approximately 1.5 hours, and although it increases to about 5 hours in anephric patients, dosage adjustment for renal insufficiency is generally not necessary. Urinary recovery of erythromycin is variable. Erythromycin is concentrated by the liver and excreted into the bile in high concentrations; some enterohepatic circulation exists. Macrolides are concentrated intracellularly in a number of cells, including macrophages and polymorphonuclear leukocytes.[21] Concentration within these phagocytic cells may be a considerable advantage in treatment of infections due to intracellular pathogens.

Both clarithromycin and azithromycin offer some pharmacokinetic advantages over any of the erythromycin preparations available, including increased stability in gastric acid, improved tissue penetration, and longer elimination half-lives, making daily or twice daily dosing effective.[22] Azithromycin pharmacokinetics are highlighted by high tissue concentrations despite relatively low serum concentrations. This is a basis for marketing this agent as a unique antibiotic, but really this is an accentuation of the pharmacokinetic properties of all macrolides.

The major adverse effect associated with erythromycin therapy is dose-related abdominal cramps, nausea, vomiting, and diarrhea.[23] Erythromycin stimulates gastrointestinal motor activity.[24] In fact, this "adverse effect" is so dependable that it has been used as a "therapeutic effect" for treatment of gastroparesis due to diabetes mellitus and progressive systemic sclerosis.[25,26] Otherwise, the incidence of adverse reactions associated with erythromycin is remarkably low. Cholestatic hepatitis occurs infrequently, most often but not exclusively is associated with the estolate preparation in adults, and occurs more commonly during pregnancy. Hypersensitivity reactions, in the form of fever, rash, and eosinophilia are rare. Transient complete hearing loss can occur, usually in patients receiving large doses parenterally.[11] Parenteral administration is not uncommonly associated with the development of thrombophlebitis. Both clarithromycin and azithromycin appear to cause less gastrointestinal irritation than does erythromycin.[27] Neither of the new macrolides appears to be associated with unique toxicity.

There are a number of important drug-drug interactions seen with therapeutic use of macrolide antibiotics about which all prescribing physicians must be aware.[19] Concomitant therapy with erythromycin increases blood levels of caffeine, nicotine, theophylline, cyclosporine, carbamazepine (Tegretol®), and disopy-

Table 1. In Vitro Antimicrobial Activity of Erythromycin, Clarithromycin, and Azithromycin*

Organism	Erythromycin		Clarithromycin		Azithromycin	
	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
Staph. aureus, methicillin susceptible	0.12	>128	0.06	>128	0.12	>128
S. aureus, methicillin resistant	>128	>128	>128	>128	>128	>128
S. epidermidis	8	>128	4	>128	16	>128
Streptococcous pyogenes	0.03	0.03	0.015	0.015	0.12	0.12
S. pneumoniae	0.03	0.03	0.015	0.015	0.06	0.12
S. agalactiae	0.06	0.06	0.06	0.06	0.12	0.12
Viridans group streptococci	0.06	0.06	≤0.008	0.03	0.06	0.12
Enterococcus species	0.5	>128	0.5	>128	2	>128
Corynebacterium species	1	16	0.25	4	16	128
Clostridium species	1	1	0.5	0.5	0.25	0.25
Propionibacterium acnes	0.03	0.03	0.03	0.03	≤0.004	0.03
Peptococcus-Peptostreptococcus sp.	0.5	4	0.25	4	0.25	2
Listeria monocytogenes	0.5	0.5	0.25	0.25	1	2
Moraxella cattarhalis	0.12	0.25	0.06	0.25	0.03	0.06
Neisseria gonorrheae	0.25	0.5	0.25	0.5	0.03	0.06
Campylobacter jejuni	0.12	1	0.25	2	0.06	0.12
Legionella pneumophila	1	2	0.12	0.25	0.5	2
Haemophilus influenzae	4	4	4	8	0.25	0.5
Bordetella pertussis	≤0.008	0.03	≤0.008	0.03	≤0.015	0.25
Bacteroides fragilis	2	4	2	2	2	2
Other Bacteroides species	0.25	4	0.25	2	0.25	1

*MIC_{50} and MIC_{90} values in μg/ml, adapted from reference 21

ramide (Norpace®). Concomitant therapy with macrolides increases the anticoagulant effect of warfarin. These interactions all result from macrolide interference with hepatic cytochrome P-450 metabolism of the other agent. Erythromycin (and presumably other macrolides as well) can increase the bioavailability of digoxin by interfering with its inactivation by microbial gut flora. Prolongation of the QT interval and associated torsades des pointes type ventricular arrhythmias can occur with concomitant administration of macrolides and terfenadine (Seldane®) or astemizole (Hismanal®). Macrolides may antagonize the antimicrobial effects of chloramphenicol and lincosamide antibiotics (lincomycin and clindamycin) by competition for ribosomal binding sites.

Let's now discuss the therapeutic indications for the macrolides, then finish with a discussion of the choices among the macrolides. A macrolide antibiotic is the therapy of choice for pneumonia due to *Mycoplasma pneumoniae* or any of the *Legionellae.* A macrolide is the therapy of choice for diphtheria or the carrier state of *C. diphtheriae.* A macrolide is the therapy of choice for pertussis. A macrolide is the therapy of choice for *Campylobacter jejuni* gastroenteritis, but therapy must be initiated within four days of onset of symptoms to be of demonstrable benefit.[28] A macrolide may have a role in treatment of *Helicobacter pylori* gastroenteritis, but discussion of the pathogenic role of Helicobacter and the efficacy of combined therapy regimens for this condition remains in rapid evolution. Macrolides are a therapy of choice for pneumonia or conjunctivitis due to *Chlamydia trachomatis.* Macrolides are a therapy of choice for pneumonia due to *Chlamydia pneumoniae* and *Chlamydia psittaci.* Erythromycin remains a useful agent for gastrointestinal tract decontamination before elective colorectal surgery (in combination with neomycin and vigorous purgation).

There are a number of situations in which erythromycin is an important alternative therapy for patients unable to tolerate the generally preferred therapy: (1) group A, C, and G streptococcal infections; (2) pneumococcal infections; (3) rheumatic fever prophylaxis; (4) prevention of bacterial endocarditis resulting from dental procedures; (5) lymphogranuloma venereum; (6) chancroid; (7) nongonococcal urethritis/cervicitis; and (8) nocardiosis (usually in combination with ampicillin). Erythromycin is important clinically as therapy for nongonococcal cervicitis or syphilis in pregnancy. Macrolides are useful alternative therapy for anaerobic pleuropulmonary infections, but clindamycin is likely a better choice.

Macrolides have become popular outpatient therapy for community acquired pneumonia. Establishing a precise microbial etiology of bacterial pneumonia remains one of the major challenges in clincial infectious diseases, and as a consequence, the precise etiology of pneumonia is usually not known. In this setting, for patients who do not require hospitalization, macrolides are reasonable empiric therapy for the primary pathogens: pneumococci, Legionellae, and Mycoplasma. The most serious concern with this empiric regimen is the marginal activity against *Haemophilus influenzae.*

The two new macrolides add some usefulness to the class in specific situations. One of these is that alluded to above: in the presence of highly suspect *H. influenzae* infection, it is reasonable to prefer either clarithromycin or azithromycin over an erythromycin preparation. Azithromycin is the only demonstrated effective single dose (1 gm PO) therapy regimen for nongonococcal urethritis and cervicitis.[29] This is useful in patients who have demonstrated noncompliance to a standard seven-day regimen of doxycycline or erythromycin or who are highly suspect for noncompliance. Clarithromycin appears active for treatment of *Mycobacterium avium intracellulare* (MAI) infection in patients with AIDS.[30] As is usually the case with mycobacterial infections, combination therapy is required to prevent the emergence of resistance to clarithromycin.[31] Both clarithromycin and azithromycin have demonstrated efficacy against murine toxoplasmosis[32,33] and are currently being investigated in clinical trials for this infection in AIDS patients (as part of combination therapy regimens). Azithromycin has demonstrated efficacy in an animal model of cryptosporidiosis[34] and is currently being investigated in clinical trials for cryptosporidiosis in AIDS patients.

Now it is time to discuss how to choose among the available macrolides. First, which erythromycin preparation should be used. Surprisingly enough, after all these years, there does not exist, in my opinion, a simple answer to this question. Erythromycin estolate does appear to achieve higher serum levels than erythromycin base, stearate, or ethylsuccinate, and there are some data demonstrating a therapeutic advantage of the estolate in pediatric populations. However, it also seems fairly clear that erythromycin estolate is most commonly associated with hepatotoxicity, probably the most serious potential adverse effect of erythromycin. I continue, therefore, to avoid the estolate in adults, and again will refrain from nonexpert opinion in pediatrics. I am unaware of any clinical demonstration of superiority of erythromycin ethylsuccinate or stearate over erythromycin base in any circumstance in adults,

and since the various preparations of erythromycin base are the least expensive, I recommend usage of erythromycin base. For intravenous administration, erythromycin lactobionate is generally used.

Now, what are appropriate indications for use of clarithromycin and azithromycin? The Medical Letter's summary statement on this issue is succinct and well stated: "Both clarithromycin and azithromycin are well-tolerated, expensive alternatives to erythromycin for treatment of streptococcal pharyngitis, community acquired respiratory infections, skin and soft tissue infections, and acute sinusitis."[27] For example the average wholesale price of a course of generic erythromycin base 250 mg PO qid for 7 days is $6.93; for clarithromycin 250 or 500 mg PO bid for 7 days is $35; and for azithromycin 500 mg PO then 250 mg PO qd days 2 to 5 is $48.78.[27] So I believe for those indications, clarithromycin or azithromycin should be reserved for patients with documented intolerance to erythromycin, until and unless data become available demonstrating superior efficacy of these agents over erythromycin and other less expensive alternative antimicrobial agents. Single dose oral therapy for chlamydial urethritis/cervicitis with azithromycin is useful, as mentioned above, in relatively unusual situations. The role of these drugs in treatment of critically problematic infections in AIDS patients (MAI infection, toxoplasmosis, and cryptosporidiosis) appears important, and is in very rapid evolution.

For the sake of completeness, troleandomycin (Tao®) is an ester of oleandomycin (a macrolide derived from *Streptomyces antibioticus)* that has been marketed in the U.S. for many years but has no usefulness in the modern antimicrobial armamentarium.

Finally, there are, of course, more macrolides in development, although no clear advantage of these newer agents over currently available agents is apparent. Spiramycin was initially reported to be useful in treatment of cryptosporidiosis, but the results of a forthcoming clinical trial for treatment of cryptosporidiosis are quite discouraging.[35] Other macrolides may have pharmacokinetic advantages that will eventually lead them into the U.S. market. Macrolides in development include roxithromycin, erythromycylamine, dirithromycin, miocamycin, and rokitamycin. Forty-one years after the discovery of erythromycin, attempts to improve the macrolides continue, but clear advantages over erythromycin remain scarce.

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Raw Oysters and Liver Disease: Two Cases of Vibrio Sepsis in Oklahoma

Daniel M. Jorgensen, MD; Patricia Quinlisk, MD, MPH; Paul N. Zenker, MD, MPH

Vibrio vulnificus naturally occurs in the marine environment and is frequently isolated from fresh seafood, particularly raw oysters. An opportunistic pathogen, it causes life-threatening sepsis in persons with underlying illnesses, particularly hepatic disease. We report two cases of *V. vulnificus* sepsis in Oklahoma, one fatal, occurring in men with liver disease who ate meals including raw oysters. Physicians should caution their susceptible patients about the hazards of consuming raw seafood, even in a noncoastal area such as Oklahoma.

Case Report 1

In August 1991, a middle-aged Oklahoma man complaining of fever, malaise, and abdominal pain was examined in a local emergency room. He had eaten a meal that included raw oysters at a local restaurant approximately 16 hours before the onset of symptoms. He had a history of hepatic cirrhosis with esophageal varices and ascites, presumably due to chronic alcohol abuse, and was on a waiting list to receive a liver transplant.

Within hours, the patient became hypotensive and expired. Blood cultures grew *Vibrio vulnificus*. An autopsy confirmed cirrhosis, ascites, esophageal varices, and erosive gastritis. Terminal sepsis was listed as the cause of death.

An investigation was initiated to determine possible sources of *V. vulnificus* and the risk to other exposed persons. The patient's raw oyster meal the night before his death was the probable source of his infection. Restaurant and shipping records indicated that the batch of oysters had been received fresh and intact. All oysters in the batch had been eaten or discarded; none was available for testing. However, other persons who ate raw oysters from the same batch did not become ill.

The Food and Drug Administration (FDA) traced the suspected batch of oysters to oyster beds located in the Gulf of Mexico, near the Louisiana coast. Because the *Vibrio* species had not been identified at the time of the FDA investigation (*V. cholerae* was a possibility), the oyster beds were sampled. Samples from six oyster beds were cultured and grew *V. vulnificus*, which would be expected in a coastal marine environment. However, none of the samples tested positive for *V. cholerae*; therefore, the oyster beds remained open for harvesting.

Case Report 2

In July 1992, a 60-year-old Oklahoma man complaining of persistent diarrhea and vomiting over the previous 3 to 4 days was admitted to an urban hospital. He had a history of chronic hepatitis B with ascites, insulin-dependent diabetes, and kidney failure, for which he had received a renal transplant in 1976. He was on long-term immunosuppressive therapy for chronic rejection of the transplanted kidney. His only exposure to raw seafood was a meal of raw oysters, which he ate at a local restaurant 10 days before admission.

His hospital course was complicated by hypotensive

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episodes, small bowel obstruction, and electrolyte abnormalities. His blood culture grew *V. vulnificus.* He improved remarkably on doxycycline and was discharged eight days after admission.

An investigation revealed that the oysters were fresh upon arrival at the local restaurant; none of them were available for testing. None of the other persons who consumed oysters from the same source became ill.

The FDA traced the suspected batch of oysters to oyster beds in Galveston Bay off the coast of Texas. These beds were known to harbor *V. vulnificus;* therefore, the beds were not tested.

Discussion

Healthy persons are unlikely to develop septicemia after ingesting food contaminated with *V. vulnificus.*[1] Thus, it was not surprising to learn that the other persons who attended the same dinner and consumed raw oysters from the same batch as these two patients did not report any subsequent illness.

However, certain persons are at high risk for developing *Vibrio* septicemia, including those with liver disease, as well as those with hematopoietic disorders, malignancies, or immunosuppressive disorders.[1] A recent study of all the *Vibrio*-related illnesses reported in Florida from 1981 to 1988 revealed an estimated age-standardized annual incidence for *Vibrio* septicemia of 82.8 per million for raw oyster eaters with liver disease, 2.0 for raw oyster eaters without liver disease, and 0.4 for non-raw oyster eaters.[2] The reason for the higher susceptibility among patients with liver disease is not clear, although poor nutrition and decreased immune function may be contributing factors. In addition, laboratory studies suggest that increased iron availability plays a role in the pathogenesis of this bacterium[3]; such iron availability is altered in patients with liver disease. High-risk persons who develop septicemia have a mortality rate of approximately 50%.[4]

V. vulnificus also can infect wounds contaminated by seawater while an individual is fishing, swimming, or handling crabs. The wound infections are characterized by redness, swelling, and a rapidly developing cellulitis. However, the risk of sepsis from a wound infection is small, even among susceptible persons, compared with the risk to susceptible individuals who eat contaminated seafood.[4]

Vibrio species occur naturally in the marine environment and may be commonly present in raw oysters.[5] The more pathogenic species, like *V. vulnificus,* increase their concentrations in spring and summer and are found in greatest number in the top 5 cm of marine sediment, according to a recent study of Florida estuaries.[6] The organism is known to survive for days in both shellstock and shucked oysters—even when stored at temperatures as low as 2°C.[7] Survival decreases when temperatures approach 0°C and below, but this seems to depend on the number of contaminating organisms per oyster.[8] Thus, fresh, cold oysters, harvested in the cooler (non-summer) months, are less likely to be contaminated; if contaminated, they are likely to have fewer viable contaminating organisms per oyster. More importantly, normal cooking procedures easily kill the *Vibrio* species, although the food must be uniformly heated. For example, organisms in the center of an oyster may survive if an oyster is partially grilled or steamed while still in its shell.

Recommendations

First, any person with a risk factor for septicemia, such as liver disease or an immunosuppressive disorder, should *never* eat raw seafood. Therefore, physicians need to repeatedly warn their high-risk patients about the hazards of eating raw seafood, particularly oysters. Furthermore, physicians need to consider the diagnosis of *V. vulnificus* sepsis in patients with rapid-onset illness following ingestion of raw oysters. Such patients should be immediately supported with intravenous fluid and started on antibiotics that include *V. vulnificus* in their spectrum, such as tetracycline. *V. vulnificus* is *not* uniformly susceptible to the aminoglycosides.

Second, although invasive disease is unlikely in healthy persons, thorough cooking is recommended for all seafood. Oysters should not be eaten raw unless freshness and appropriate storage temperatures can be assured, which is difficult in land-locked areas such as Oklahoma, where transportation from coastal areas may be prolonged.

Finally, persons with open sores or wounds should avoid direct contact with sea water, if possible. If someone is cut or injured in a marine environment, the wound should be washed immediately, and a topical antiseptic should be applied. If signs of infection appear, a physician should be contacted.

Postscript

This investigation revealed that the first patient had been warned of the risks associated with eating raw seafood. However, his wife reported that he had a passion for raw oysters and continued to consume them at least once a week, in spite of his underlying liver disease. The second patient claimed he was not aware of the hazards associated with eating raw seafood. He refrained from eating raw fish because he did not like

the taste; however, he continued to eat raw oysters throughout his adult life, in spite of his chronic liver disease, renal transplant, and long-term use of immunosuppressive medications.

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Vision Quality of Elderly Oklahomans

Carol Blackwell Imes, MD; Carolyn Peck, PhD

The purposes of this study are to determine if age related visual changes are affecting the ability of older adults to perform everyday tasks, to identify histories of eye diseases/eye surgeries, and to document eye care practices.

Our sample was obtained from the Third Age Life Center at Baptist Medical Center in Oklahoma City. The survey was mailed to 14,856 members; 848 (6%) surveys were returned.

Over 84% of the respondents have never been diagnosed with dry eye syndrome, glaucoma, macular degeneration, or diabetic retinopathy. Sixty percent rated their health and vision quality as good. Females expressed more vision problems than males. Advanced age (75 years or older) did increase likelihood of experiencing eye diseases and vision difficulties.

The majority of respondents in this study appear to be experiencing healthy vision with minimal age-related changes and have not been diagnosed with the eye diseases characteristic of this age group. Evidence of regular eye examinations was reported, with 33% of the respondents reporting having eye exams once a year and 33% twice a year.

As individuals age, there is a gradual decline in all physiological functions. Age-related visual changes begin in mid-life and progress gradually. With the advancing age of the general population, increasing numbers of older persons will experience age-related visual disorders. These visual disorders include cataracts, glaucoma, macular degeneration, and diabetic retinopathy.[1]

According to the National Center for Health Statistics, the diagnosis of cataracts increases as age increases. Eighteen percent of patients age 65 through 74 years have been diagnosed with cataracts. This increases to 46% in the 75 to 84 years category. Glaucoma occurs in 2% of the population over the age of 40 years. Macular degeneration is the leading cause of blindness in the over-60 population, and cataracts are second.

Visual impairment can also affect an older person's mental wellness. Diminished visual acuity can result in depression, social isolation, and a lower level of social interaction. Visual loss can create mobility problems and an increased likelihood of falls.[2]

To the knowledge of the authors, no baseline data have been collected concerning the vision quality of elderly Oklahomans. The purposes of this study are: (1) to determine if age-related visual changes are affecting the ability of older adults to perform everyday tasks; (2) to identify histories of eye diseases/eye surgeries; and (3) to document eye care practices.

Methods

The sample for this study was obtained by surveying members of the Third Age Life Center, a hospital-based geriatric membership program sponsored by Baptist Medical Center, located in Oklahoma City. Any individual aged 55 years or older is eligible for membership benefits, which include case management, health/wellness programs, and discounts on hospital services.

The survey used for this study is a modified version of

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an instrument developed by Russell, Sekular, and Ketenhour.[3] Participants in the study responded to 41 questions. The questions included basic sociodemographic information, documentation of eye care practices and eye surgeries, and a variety of statements that asked respondents to rate either the frequency or the degree of difficulty experienced while performing routine tasks. For ratings of frequency of difficulty, scores were 1 (Never), 2 (Rarely), 3 (Occasionally), and 4 (Frequently). For ratings of degree of difficulty, scores were 1 (None at all), 2 (Little), 3 (Quite a bit), and 4 (A lot).

The survey was mailed in the fall of 1990 to 14,856 members of the Third Age Life Center as a supplement to their quarterly newsletter. The 848 surveys returned represented a 6% rate of return. Simple percentages and frequencies were calculated for each of the 41 variables. The Chi-square statistical test was also used to determine if any differences in vision existed between certain groups in the samples. Sex and age of respondents were employed to determine if any statistically significant differences occur between these sociodemographic variables and the vision-related variables. For analysis by age, responses were grouped in two different ways: (1) respondents ≤65 or ≥75 years of age, and (2) respondents 65-75 years of age.

Results

Percentage and frequencies were calculated for each variable (Table 1).

The ages of the 848 respondents range from 55 to 93 years, with 50% being in the 70 to 79 category. Seventy percent of the sample were female, 85% were unemployed (retired), and 94% still drive a car.

Over 85% reported *never* having been diagnosed with the following eye diseases: dry eye syndrome, glaucoma, macular degeneration, diabetic retinopathy, or retinal abnormality. Thirty-seven percent (N=315) have been diagnosed positively for cataracts, and 15% (N=125) have undergone cataract surgery. The largest percentages selected their eye care professional either by a referral from a friend (45%) or from their family physician (29%). Sixty percent of the sample rated both their overall health and their vision quality as good. Twenty-one percent rated their health as fair, and 27% rated their vision quality as fair. Respondents reported having their vision tested either once per year (33%) or every two years (33%).

Over 50% indicated having *little or no* difficulty with following: blurry vision when reading (83%), eye strain (83%), losing their place while reading (87%), being more aware of their vision (60%), noticing a difference between eyes (75%), blurring of distant objects (80%), difficulty judging distances (82%), trouble driving at night (61%), being blinded by car headlights (54%), difficulty seeing in dim light (65%), and trouble adapting to bright lights (78%).

Over 75% of respondents reported experiencing *no difficulty* with the following: driving in the daytime

Table 1. Percentage and Frequencies of All Variables

Variable	%	N
Age of Respondent		
55-59	1.97	17
60-64	4.53	39
64-69	14.75	127
70-74	26.71	230
75-79	24.16	200
80-84	16.49	142
85-89	8.36	72
≥90	3.02	26
Sex of Respondent		
Male	28.55	245
Female	71.45	613
Employment Status		
Yes	14.29	123
No	85.71	730
Drive a Car		
Yes	94.31	812
No	5.69	49
Diagnosis of Eye Disease		
Dry Eye Syndrome		
Yes	15.62	134
No	84.38	724
Cataracts		
Yes	36.71	315
No	63.29	543
Glaucoma		
Yes	6.76	58
No	93.24	800
Macular Degeneration		
Yes	7.46	64
No	92.54	794
Diabetic Retinopathy		
Yes	1.17	10
No	98.83	848
Eye Surgeries		
Cataract		
Yes	14.81	125
No	85.19	719
Glaucoma		
Yes	2.25	19
No	97.75	826
Cornea Transplant		
Yes	1.78	15
No	98.10	828
Vision Quality		
Excellent	10.14	87
Good	60.02	515
Fair	27.16	233
Poor	2.56	22
Health Quality		
Excellent	14.88	128
Good	60.93	524
Fair	21.40	184
Poor	2.79	24

Continued

Table 1. Percentage and Frequencies of All Variables *(continued)*

Variable	%	N
Frequency of Vision Testing		
Twice a year	11.69	99
Once a year	33.29	282
Every two years	33.53	284
Three to four years	21.37	181
Selection of Eye Care Professional		
Friend	44.85	366
Family doctor	29.41	240
Hospital referral	2.21	18
Advertisement	1.47	12
Location	8.58	70
Phone Book	1.84	15
Blurry Vision When Reading		
None	38.33	322
Little	45.36	381
Quite a bit	12.02	101
A lot	4.29	36
Eye Strain		
None	36.51	303
Little	47.35	393
Quite a bit	11.93	99
A lot	4.22	35
Lose One's Place While Reading		
None	50.12	414
Little	37.29	308
Quite a bit	9.08	75
A lot	3.51	29
More Aware of One's Vision		
None	18.53	151
Little	41.60	339
Quite a bit	24.91	203
A lot	14.97	122
Difficulty Driving in the Daytime		
None	81.47	644
Little	15.46	126
Quite a bit	1.47	12
A lot	1.60	13
Notice Difference Between Eyes		
None	48.68	407
Little	27.51	203
Quite a bit	11.60	97
A lot	12.20	102
Tendency to Use Only One Eye		
None	75.06	602
Little	13.20	109
Quite a bit	5.93	49
A lot	5.81	48
Distant Objects Blurry		
None	44.13	372
Little	36.30	306
Quite a bit	11.51	97
A Lot	8.07	68
Difficulty Judging Distances		
None	42.84	359
Little	39.14	328
Quite a bit	10.62	89
A lot	7.40	62
Trouble Driving at Night		
None	19.65	159
Little	41.53	336
Quite a bit	21.14	171
A lot	17.68	143
Car Headlights Blinding		
None	13.32	110
Little	40.44	334
Quite a bit	26.15	216
A lot	20.10	166
Difficulty Seeing In Dim Light		
None	22.22	184
Little	43.24	358
Quite a bit	23.19	192
A lot	11.35	94
Run into Doors, Posts & Walls		
None	79.14	660
Little	16.79	140
Quite a bit	3.12	26
A lot	.96	8
Bump into People in Crowded Places		
None	79.64	665
Little	17.49	146
Quite a bit	1.92	16
A lot	.96	8
Bump Head		
None	81.27	667
Little	15.73	131
Quite a bit	2.52	21
A lot	.48	4
Trouble Adapting to Bright Lights		
None	31.82	266
Little	45.93	384
Quite a bit	13.88	116
A lot	8.37	70
Read More Slowly		
Never	26.66	221
Rarely	30.16	250
Occasionally	31.72	263
Frequently	11.46	95
Hobbies Are More Difficult		
Never	32.92	268
Rarely	27.76	226
Occasionally	27.40	223
Frequently	11.92	97
Difficulty Going Downstairs		
Never	39.13	322
Rarely	26.25	216
Occasionally	24.06	198
Frequently	10.57	87
Take Longer On Visual Tasks		
Never	25.00	202
Rarely	33.04	267
Occasionally	30.32	245
Frequently	11.63	94
Take Longer Recognizing Objects		
Never	31.23	258
Rarely	33.78	279
Occasionally	27.00	223
Frequently	7.99	66
Lack Confidence on Visual Tasks		
Never	40.78	334
Rarely	30.65	251
Occasionally	21.86	179
Frequently	6.72	55
Trouble Reading Street Signs		
Never	30.17	251
Rarely	30.53	254
Occasionally	26.08	217
Frequently	13.22	110
Difficulty Sort Dark Colors		
Never	41.96	347
Rarely	27.45	227
Occasionally	21.52	178
Frequently	9.07	75
Trouble Seeing Friend in a Crowd		
Never	40.58	334
Rarely	34.26	282
Occasionally	19.20	158
Frequently	5.95	49
Trouble Seeing in Strong Light		
Never	30.29	249
Rarely	26.28	216
Occasionally	28.95	238
Frequently	14.48	119
Trouble With Glare		
Never	17.23	142
Rarely	26.21	216
Occasionally	33.86	279
Frequently	22.57	186
Trouble Recognizing Distant Objects		
Never	19.47	162
Rarely	28.25	235
Occasionally	34.50	287
Frequently	17.67	147
Trouble Watching Television		
Never	55.26	462
Rarely	28.71	240
Occasionally	13.16	110
Frequently	2.87	24
Trouble Seeing Objects at Night		
Never	17.05	142
Rarely	27.61	230
Occasionally	34.33	286
Frequently	20.89	174

(81%), using one eye (75%), running into doors, posts, or walls (79%), bumping into people in crowded places (79%), or bumping their head (81%).

Respondents reported experiencing with some frequency (occasionally/frequently) the following: trouble with glare (56%), trouble recognizing distant objects (52%), and trouble seeing at night (55%).

For the remaining 11 variables in this category, over 50% of the respondents reported either never or rarely experiencing the following: reading more slowly, taking longer on visual tasks, finding hobbies more difficult, having difficulty going down stairs, taking longer to recognize objects, lacking confidence on visual tasks, having trouble reading street signs, having difficulty sorting dark colors, having trouble seeing a friend in a crowd, having difficulty seeing in strong light, and having trouble watching television.

Table 2. A Comparison of Statistically Significant Vision Quality Variables by Sex of Respondent

Variable	Level of Significance	Degrees of Freedom	Chi Square
Hobbies are more difficult	.05	3	7.942
Difficulty going down stairs	.00	3	13.359
Trouble seeing in strong light	.05	3	7.817
Trouble seeing with glare	.04	4	10.060
Trouble recognizing distant objects	.03	4	10.385
Difficulty judging distances	.02	3	10.194
Car headlights blinding	.00	3	14.352
Bump head	.00	3	28.077
Trouble adapting to bright lights	.05	3	7.668
Driving at night	.02	3	9.245

Table 3. A Comparison of Statistically Significant Vision Quality Variables by Age of Respondent (≤ 65 ≥)

Variable	Level of Significance	Degrees of Freedom	Chi Square
Cataract diagnosis	.00	1	34.846
Macular degeneration diag.	.00	1	9.344
Cataract surgery	.00	1	8.339
Vision testing	.04	1	10.332
Read more slowly	.03	3	9.040
Trouble seeing a friend in a crowd	.00	3	16.066
Trouble seeing in strong light	.05	3	7.805

Chi-Square Analysis

Ten of the thirty variables testing for either frequency of difficulty or degree of difficulty with vision were found to indicate significant statistical differences when compared with the sex of the respondent (Table 2). Females reported more vision problems than males. Females indicated greater difficulty than males with the following: hobbies, going down stairs, seeing in strong light, recognizing distant objects, judging distances, and driving at night.

Males indicated greater difficulty than females with the following: being blinded by car headlights, adapting to bright lights, and bumping their head. Twenty of the vision-related variables showed no significant difference when compared with the sex of the respondent.

Age was compared with the surveyed variables in two different ways: (1) those respondents whose age was 65 years or more, and those whose age was 65 years or less; (2) respondents whose age was greater than or equal to 75 or less than or equal to 75. Seven of the vision-related variables were found to have significant statistical differences when the age division began at 65 (Table 3). Older respondents (65 and older) have been diagnosed more frequently with cataracts and macular degeneration than the younger respondents (65 and younger). Also, more of the older respondents have undergone cataract surgery. They also reported having their vision tested more frequently, as well as experiencing greater difficulty with read-

Table 4. A Comparison of Statistically Significant Vision Quality Variables by Age of Respondent (≤ 75 ≥)

Variable	Level of Significance	Degrees of Freedom	Chi Square
Cataract diagnosis	.00	1	69.252
Glaucoma diagnosis	.00	1	10.495
Macular degeneration diag.	.02	1	5.254
Vision quality	.02	4	11.204
Overall health quality	.03	3	8.773
Frequency of vision testing	.02	4	11.204
Hobbies more difficult	.03	3	8.598
More aware of vision	.01	3	10.033
Bright lights	.01	3	9.96
Cataract surgery	.00	1	42.203
Glaucoma surgery	.04	1	4.194

ing, seeing friends in a crowd, and seeing in strong light. Of the 30 vision-related variables, 23 in the 65 and older age range showed no significant statistical differences.

Eleven of the vision-related variables were found to have significant statistical differences, with the age division beginning at 75 (Table 4).

These respondents (75 and older) were found to have been diagnosed more frequently with glaucoma, cataracts, and macular degeneration. More of them had experienced cataract and glaucoma surgery, as compared to those younger than 75. They reported a lower rating of their overall health and vision quality, as well as experiencing greater difficulty with their vision when working on hobbies and in adapting to bright lights. They also indicated they were more aware of their vision.

Conclusion

1. The majority of individuals participating in this study appear to be experiencing healthy vision with minimal age-related changes.

2. The majority of the respondents have not been diagnosed with glaucoma, diabetic retinopathy, macular degeneration, dry eye syndrome, or retinal abnormality. Thirty-seven percent have been diagnosed positively for cataracts.

3. The initial development of cataracts is possibly indicated with the following reported problems: little trouble driving at night (42%) and in dim light (23%), and little trouble adapting to bright lights (46%).

4. Evidence of regular eye examinations was reported, with 33% of the respondents having exams once a year and 33% two times a year.

5. Advancing age (75 years or older) did increase respondents' likelihood of experiencing eye diseases and vision difficulties.

6. Given that the incidence of eye disease and vision problems is virtually the same for men and women, it appears that women are more willing to admit to the existence of visual problems and/or are more aware of their visual limitations.

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Tulsa Sexual Assault Nurse Examiners (SANE) Program

Mark Thomas, MD; Helenmarie Zachritz , MA

This article describes the implementation of a new program in the Tulsa Police Department which utilizes highly trained registered nurses to do forensic examinations on victims of rape in that community. The program is a multidisciplinary effort among various medical, legal, and law enforcement entities in Tulsa, with coordination provided by the mayor's office. With a consistent as well as experienced corps of forensic nurses conducting most of the rape examinations, the quality of the forensic evidence has increased dramatically, which enables the judicial system to more effectively prosecute rapists.

THE Tulsa Sexual Assault Nurse Examiners Program (SANE) is a program initiated by the Tulsa Police Department which utilizes a corps of highly trained forensic nurses to collect evidence from rape victims. The program is coordinated through the Tulsa Police Department's Sex Crimes Unit and the mayor's office and is a multidisciplinary effort among seven different organizations in Tulsa: the Police Department, Call Rape (rape crisis center), Hillcrest Medical Center, University of Oklahoma College of Medicine, the District Attorney's Office, the Victim/Witness Center, and the Tulsa City/County Health Department. The coordinator is a member of the mayor's staff, which assures the program high visibility and community support.

From January through March of 1992, Oklahoma experienced a 44% increase in rapes. In Tulsa, 412 persons reported being raped in 1991. Through November 1992, 344 rapes were reported. Before the SANE program began in July of 1991, rape victims in Tulsa County were taken to hospital emergency rooms in one of five hospitals in Tulsa. What happened there was what happened in most emergency rooms in most hospitals in the state—the victim was made to wait a significant period of time, perhaps even several hours, in a public setting with a police officer until more pressing and urgent medical emergencies were taken care of and the emergency room physician had time to examine and treat the rape victim. While the victim waited, sometimes up to twelve hours, she was not allowed to urinate, drink anything, shower, or change her clothes—nothing that would alter or destroy physical evidence. The police officer was also delayed. He could not leave the victim until the examination was completed, and he had the rape kit in hand to preserve the chain of evidence. Added to all of this, emergency room physicians have been reluctant to do rape examinations because of the time involved—two to three hours to complete the kit—followed by the possibility of court testimony later on, necessitating even more time away from their practices.

The Tulsa Police Department, along with the Call Rape crisis center, developed the idea of using registered nurses to do forensic examinations away from busy emergency rooms. Hillcrest Medical Center offered a suite of rooms and the requisite medical supplies and nursing coordination. Twenty nurses completed the necessary training and on July 1, 1991,

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the program began. It was well received by police officers who bring the victim to the hospital examination area where they are met by the sexual assault nurse examiner and a rape crisis counselor. The examination is done immediately in an area designated solely for rape examinations. The suite is equipped with a waiting area for the police and families, and has coffee, snacks, and telephones. After the examination the victim can shower, change into fresh clothing, and receive follow-up information for counseling and medical treatment. The hospital OB-GYN resident is available to the nurse examiner at all times if there is a need for a medical evaluation and treatment. Of course, if the victim has serious injuries that require emergency medical treatment, she will be taken to the nearest hospital for care and the examination will be done at that hospital, not at the SANE facility. The program's medical director is available to be called for questions that arise during an examination and for follow-up treatment if necessary. He reviews all medical and forensic records on a monthly basis. The SANE nurse normally completes the full examination on her own. To date, SANE nurses have completed over 400 examinations. The Tulsa Police Department's forensic chemist reports a vast improvement in the quality of evidence collection since the nurses started doing the rape examinations. In fact, the SANE program examinations are of such a high quality that Tulsa District Attorney David Moss has designated Tulsa SANE nurses as expert witnesses. Although only two SANE nurses have testified to date, both of these cases resulted in convictions. In 1991 SANE received a U.S. Justice Department Award for Public Service. Residents training in emergency medicine at Tulsa Regional Medical Center observe SANE nurses as part of their elective curriculum.

The nurses are paid $100 for each examination by the Oklahoma Crime Victims Compensation Board, Sexual Assault Examination Fund. Hillcrest Medical Center is reimbursed $50 for every examination from the same fund to cover the cost of supplies and medications in the examination room. The nurses are also paid $100 by the district attorney for their courtroom testimony. Tulsa SANE is currently working with Oklahoma City, Claremore, Woodward, and other communities to assist them in setting up similar programs. It is a simple concept but one that requires community support and cooperation.



STEVE JENNINGS

The nurses are employed at various hospitals and clinics in Tulsa but sign up to be on-call during their off-hours. They are paid only for doing an examination. SANE covers evenings, weekends, and all holidays. OB-GYN residents at O.U. College of Medicine in Tulsa examine victims during weekdays. Because most examinations are conducted in the evening and during weekend hours, the SANE program is examining 95% of all rape victims in Tulsa.

The Tulsa Police Department supplies pagers for the nurses, and Call Rape dispatches the nurses when they are called for a rape crisis counselor. SANE currently averages 20 examinations a month.

(Standing) Gay Pasley-Richards, Call Rape advocate; Louis Arce, Tulsa police officer; Kathy Bell, director of Medical Surgical Services at Hillcrest; and (seated) Allison Beach, sexual assault nurse examiner.

(Photograph reprinted by permission *Crest* Magazine Spring 1993, and Hillcrest Medical Center, Tulsa, Oklahoma.)

There are 17 active forensic nurses in Tulsa and 14 additional nurse examiners are being trained. As mentioned before, some of these new trainees are from Oklahoma City, Shawnee, Claremore, Woodward, and even Arkansas.

Rape victims respond very well to a woman examiner. With the compassionate and committed forensic nurses that operate the Tulsa SANE Program, it is hoped that more women will report their sexual assault and more rapists will be arrested and convicted.

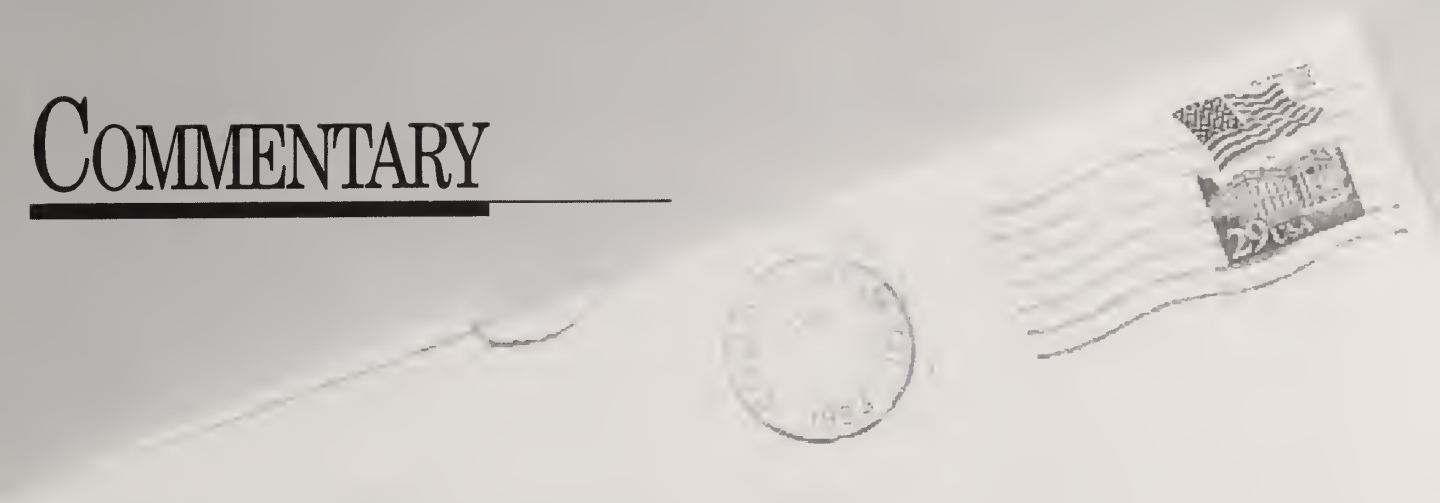
A new statewide effort has begun as a result of Tulsa's initiative. The Tulsa SANE Program is the only one of its kind in Oklahoma and is currently working to establish other programs throughout the state with a grant from the Oklahoma Department of Mental Health and Substance Abuse. At the national level, Tulsa SANE was among 31 programs which met last August in Minneapolis for the first national sexual assault nurse examiner program meeting. The organization was formalized and adopted the name International Association of Forensic Nurses. A quarterly newsletter will be published and an executive committee was elected to work with the American Nursing Association to develop standards for certification of forensic nurses. The ultimate goal of this work is to collect evidence of the highest quality while providing compassionate, professional, and timely care of sexual assault victims.

The Authors

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Helenmarie Zachritz is a member of the mayor's staff currently assigned to the Tulsa Police Department to implement and coordinate the SANE Program for the City of Tulsa.

COMMENTARY



A Letter to the Clintons About Lawyers and the Principles of Managed Competition

Dear President Clinton and Ms. Hillary Rodham Clinton:

I write to you as a doctor speaking to a pair of lawyers who champion U.S. health care reform. Congratulations. To begin with, I congratulate you on your courage, your energy, and your sheer gall in taking the huge political gamble to restructure the health care policy of the United States in 100 days. It takes a pair of huge crystal balls, perhaps even two pairs, to do what you're doing.

The health care industry makes up one-sixth of the U.S. economy. Your confidence that you can redraw the entire labyrinthic health care system in such a short time with 531 eager beaver experts from academia and from inside the beltway boggles my mind and takes my breath away. Complexity is putty in your hands.

That you are doing this without advice from those now running the system—hospital administrators, physicians, health insurance executives, and pharmaceutical leaders—further astonishes me.

The Three H's—Hillary, Health Care, and Hubris

Political pundits predict the three H's—Hillary, Health care, and Hubris—are most likely to do your administration in. Well, you've got a hell of a lot of H's on the line. I wish you luck. You'll need it. So far your hubris has managed to alienate the health care establishment, the pharmaceutical industry, Republican Congressmen and Senators, and even such stalwart Democrats as Metzenbaum, Stark, and Rostenkowski. But I suppose if you're world class policy wonks who know almost anything about everything, you have to flaunt your policies and your wonks.

A Fair Share of Sacrifice by Lawyers

All I'm really asking in this letter is for you and other members of the legal profession to make your fair share of sacrifice. After all, there are one million lawyers in the U.S. making about $100,000 each, compared to 600,000 doctors making an average of $160,000. We're both contributing equally to the deficit. Lawyers may have a slight lead in deficit-blame since 70 percent of Congressmen and Senators are lawyers. You're the people who appropriate the money. You've also been responsible for $150 billion a year spent by doctors on "defensive medicine" to avoid an "offensive legal system."

Two Modest Proposals

Just to make sure doctors and lawyers are on a level playing field, i.e., contributing equally to erasing the deficit, here are a few modest proposals you may wish to consider:

1. In the first place, you ought to form a Legal Reform Task Force. A physician in Jackson Hole, Wyoming—where the whole theory of "managed competition" was born at the home of Paul Ellwood, father of the HMO, the PPO, outcomes management, and managed competition—made this suggestion in an April 12 Letter to the Editor in *Newsweek* magazine:

"Since Hillary Rodham Clinton, a lawyer, heads the task force on health care reform and will conduct policy-formulating sessions in private, excluding the American Medical Association and other health care organizations, it would be a sign of evenhandedness for President Clinton to appoint a physician to chair a national task force on tort reform. The task force would, of course, conduct policy-development sessions in private, excluding such legal organizations as the American Bar Association and the Association of Trial Lawyers of America."

—Roland Fleck, MD
Jackson Hole, Wyo.
Newsweek, *April 12, 1993*

That's all we doctors are requesting on the part of you lawyers—evenhandedness.

2. Secondly, you ought to take under advisement the idea of introducing a system of "managed competition" for lawyers. "Managed competition," as applied to lawyers, would be quite simple:

"The central idea would be to divide lawyers and law firms into competing economic units, called "accountable legal partnerships," that would contract with insurance-purchasing cooperatives to provide standardized packages of legal benefits for fixed per capita rates. Thus, managed competition would hasten the demise of fee-for-service payment, require legal providers to bundle other services into defined benefits plans, and by remunerating lawyers at fixed rates, place them at financial risk for their performance. Taken together with other proposed reforms—presumably some form of global expenditures—managed competition would lead to a restructuring of the legal care system unprecedented in the United States."

Don't Let These Proposals Make You Uneasy

These two proposals may make you uneasy. Fear not; the proposals are for the public good. You will be in the hands of a beneficent government. The proposals rest on the assumption that you are not a profession but an industry driven by perverse economic incentives. When you are placed on salary, stripped of your autonomy and your control, these incentives will disappear, and you will feel good about yourselves again.

Comprehensive Fees, Not Fees For Each Service

Don't worry, you will receive an annual premium for comprehensive services, not a price for each service. The government will decide what is a fair capitated price. No longer will you have to bill for time spent on the phone, or the time consumed for difficult cases. The clock will no longer be running.

All cases will be the same in the eyes of the government—you alone will know that some cases are tougher than others. All fees, of course, will be the same for junior and senior partners.

An Egalitarian Profession

You will then be in an egalitarian profession—without payment differentials based on experience and skills acquired over a lifetime. Your Accountable Legal Partnerships (ALPs) will respond to bids issued by LIPCs (Legal Insurance Purchasing Cooperatives), which will make sure each citizen receives legal services at a reasonable price, or else you will be at financial risk. By the way, if some of your clients are of questionable character or represent someone with whom you have had bad pre-existing experiences, you'll have to take them as clients anyway.

No Favors for Friends, Relatives, or Associates

One final point. You'll have to treat all your clients the same—no favorable treatment just because they're relatives or associates. Let me give two examples of abuses of the system in the medical field. Under the new rules, your father, Hugh Rodham, Mrs. Clinton, would not have been allowed to stay in the hospital for three weeks prior to his death from a stroke. Medicare recommends discharge in three or four days, or after 10 days with complications. Your father, according to Medicare rules, received a level of hospital care well beyond the norm for his condition, a level that would be considered outrageously expensive in the brave new world of health care reform.

The elderly now consume 40 percent of all the health care dollars in the U.S. As Victor Fuchs, economist at Stanford, has written in a previous letter to your husband (Fuchs V. Commentary: Dear President Clinton. *JAMA* 269:1678-1679, 1993):

"No nation can afford a health policy that provides the elderly with all the care that might do some good without regard to cost."

Another example of what will have to change is the treatment recently afforded Secretary of Defense Les Aspin. When Secretary Aspin promptly had a pacemaker inserted after a heart problem, you said, Mr. President, "Well, *anybody* can have a pacemaker."

Don't be so sure, Mr. President. Pacemakers require skilled surgeons and a high tech company that makes a profit in order to make the pacemaker and an insurance company motivated to pay the bill. In the future, I trust Mr. Aspin and other members of your Administration will have to subject themselves to the normal waiting period, rather than jumping the queue. I assume also that the pacing device will be made by the lowest bidder, that the medications will be the cheapest available, that the doctors will be paid with frozen fees, and that the recovery period will be only that allowed by the government.

All I'm really asking for is a fair sacrifice on the part of lawyers, their relatives, and the members of their Administration, should these lawyers rise to the positions of President and First Lady.

One concluding point, if I may. Under the new system of "managed competition" for lawyers, you will no longer be addressed as "lawyers," "attorneys," "esquires," "counselors," or even as "Mr. President" or "First Lady." Under the new system, we won't professionalize people or distinguish them by dint of their title or education.

Instead you will be called "legal providers." In your case, I'm sure your own bureaucracy could see fit to address you as "preferred legal roviders," since 43 percent of the people elected you.

Respectfully yours,
Richard L. Reese, MD
Oklahoma City

Note: Dr. Reese is the former editor-in-chief of Minnesota Medicine. *A pathologist, he now lives in Oklahoma City and continues to publish a monthly newsletter,* The Reese Report.

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NEWS

Tulsa storms don't stop OSMA's Annual Meeting

A Saturday night tornado in Tulsa didn't stop the Inaugural Ball at this year's OSMA Annual Meeting, nor did it put a damper on the remainder of the proceedings.

Saturday night, April 23, as scheduled, Tulsa oncologist G. Lance Miller, MD, became the 88th president of the Oklahoma State Medical Association. He succeeds James D. Funnell, MD, Oklahoma City obstetrician-gynecologist.

The gala also honored Karen (Mrs. Dennis) Mask, new president of the OSMA Auxiliary, and her immediate predecessor Judy (Mrs. Carl) Critchfield. The evening's entertainment featured Robert S. Eliot, MD, speaking on stress management in a program entitled "Is There Life After Medical School?" Dr. Eliot is director of the Institute of Stress Medicine, Denver, and author of *Stress: Is It Worth dying For?*



James D. Funnell, MD (l), presents the president's gavel and medallion to his successor, G. Lance Miller, MD.

New Officers. Added to the association's roster of officers during Closing Session elections on Sunday, April 25, were Jay A. Gregory, MD, Muskogee surgeon, president-elect; Larry L. Long, MD, Oklahoma City surgeon, vice-president; Carol Blackwell Imes, MD, Oklahoma City ophthalmologist, secretary-treasurer; Douglas C. Hubner, MD, Tulsa pathologist, chair, Board of Trustees; and Ron M. Kreger, MD, Ponca City obstetrician-gynecologist, vice-chair, Board of Trustees.

(In early May, Dr. Long officially resigned his post as speaker of the house. In accordance with association bylaws, Vice-Speaker Mary Anne McCaffree, MD, will move up to serve out the year remaining in his term. Dr. Miller appointed Perry A. Lambird, MD, Oklahoma City, to fill Dr. McCaffree's vacated post and serve out the year remaining in the vice-speaker's term.)

Added or retained as OSMA trustees were Clarence Robison, Jr., MD, Oklahoma City, District VI; Robert H. Hayes, MD, Atoka, District XI; and Gary L. Paddack, MD, Ada, District XII. Alternate trustees are Royice B. Everett, MD, Oklahoma City, District VI; Fred M. Ruefer, MD, Muskogee, District IX; Jone Kendrick, MD, Idabel, District XI; and James V. Miller, MD, Ardmore, District XII. All will serve three-year terms.

Earning new two-year terms as delegates to the AMA were Ed L. Calhoon, MD, Beaver; William O. Coleman, MD, Oklahoma City; Norman L. Dunitz, MD, Tulsa; and Michael J. Haugh, MD, Tulsa. Drs. Sara Reed DePersio, Oklahoma City; Gary F. Strebel, Oklahoma City; Edward J. Tomsovic, Tulsa; and Gregory will serve as alternate delegates.

Serving on the PLICO Board of Trustees will be Drs. Shelby D. Barnes, Oklahoma City; Billy Dale Dotter, Okeene; John A. McIntyre, Enid; Tim K. Smalley, Stillwater; Kenneth W. Whittington, Bethany; and Funnell.

Awards. At the Inaugural Banquet, Dr. Funnell presented three Presidential Citations to individuals he felt were deserving of special recognition for their support and contributions to medicine during his term in office. Recipients were Oklahoma City attorney Andy Coats, immediate past president of the Oklahoma Bar Association; OU College of Medicine professor and psychiatrist Gordon H. Deckert, MD; and William G. Bern-

Annual Meeting *(continued)*

hardt, MD, for his work on the Council on Member Service.

A number of other awards were presented during the Opening Session of the House of Delegates on Friday, April 23. Ms. Pat Maly, Enid, was honored as the Donald J. Blair Friend of Medicine (formerly Layman of the Year Award) for her community television program featuring local physicians. Former state Commissioner of Health Joan K. Leavitt, MD, Oklahoma City, received the Wyeth-Ayerst Physician Award for Community Service. Also presented were the Charlotte S. Leebron Award to Ronald A. Greenfield, MD, Oklahoma City, for writing the best scientific paper published by the JOURNAL in 1992, and the JOURNAL's Best Cover Photo Award to William S. Harrison, MD, Chickasha. Receiving plaques in appreciation for their service as delegates to the AMA were Billy Dale Dotter, MD, Clarence Robison, Jr., MD, and Burdge F. Green, MD.



Dr. Carol Blackwell Imes speaks at the candidates' forum prior to her election as OSMA secretary-treasurer.

Life Members. The following eleven applicants were named OSMA Life Members: James K. DeVore, MD; Dan E. Woodson, MD; James T. Boggs, MD; Charles Cathey, MD; Roberta Edwards, MD; Arthur Elliott, MD; Sidney Schnitz, MD; and Carl W. Smith, Jr., MD; from Oklahoma City; and Bill J. Reynolds, MD, Midwest City; Mabelle Collins, MD, Edmond; and Walter Honska, MD, Stillwater.

Auxiliary. Joining newly installed President Karen Mask, Edmond, in heading the OSMA Auxiliary will be Maggie Hubner (Douglas), Tulsa, president-elect; "K" Caldwell (Tim), Tulsa, first vice-president; Pat Jenkins (Randall), Chickasha, second vice-president; Abby King (Kent), Marlow, recording secretary; Debbie Glasgow (James), Ada, treasurer; and Barbara Jett (Mason), Oklahoma City, treasurer-elect. OSMAA regional vice-presidents are Suzanne Ballard (Noble), Region I; Rosalie Rahe (Gary), Oklahoma City, Region II; Barbara Nonweiler (Edward), Tulsa, Region III; and Sharon Gauthier (Wilfred), Ardmore, Region IV.

Exhibitors and Contributors. The OSMA Annual Meeting featured exhibitors and contributors again this year, and their presence added greatly to the festive atmosphere in the lobby of the Adam's Mark Hotel, focal point of the meeting. For helping to make this year's meeting a success; for adding to the T-shirt, mug, cap, visor, paper clip, and notepad collections of everyone in attendance; and for keeping energy levels high with cookies, mints, and even meals, the following organizations deserve another thank you: American Diabetes Association; American Medical Disposal, Inc.; Bank of Oklahoma; Cancer Center of the Southwest; Baylor Institute for Rehabilitation; C.L. Frates and Company; American Home Health Services, Inc.; Children's Medical Center; Diagnostic Neurophysiology, Inc.; Fusion, Inc.; Harrison Associates, Inc.; I.C. Systems; Laser Tek; Laureate Psychiatric Hospital; Manor Health Care; McNeil Pharmaceutical; Medical Arts Laboratory, Inc.; Merrill Lynch; Oklahoma State Department of Health; Organon Pharmaceuticals; Ortho Pharmaceuticals; Pfizer Lab; Presbyterian Hospital; Professional Office Management, Inc.; PVS Medical Systems; SHARE, Psychiatric Day Treatment Center; Southwestern Bell Mobile Systems; Stillwater National Bank and Trust Company; The Bethany Pavilion; Turnkey Computer Systems, Inc.; University of Oklahoma Health Sciences Center Libraries; and Wyeth-Ayerst Pharmaceuticals.



At the Inaugural Banquet, Dr. Robert S. Eliot provides both humor and information about coping with stress.

Resolutions a major agenda item at Tulsa meeting

Resolutions and their disposition are always prominent on the business agenda when the OSMA House of Delegates convene.

At this year's Annual Meeting in Tulsa, three reference committees and the House of Delegates considered 28 resolutions. When the dust had settled, 17 resolutions had been adopted as submitted and 6 were adopted after being amended. Five were rejected. Resolutions 3, 12, 20, and 24 were then forwarded to the AMA House of Delegates, meeting this month in Chicago.

Among the items approved were resolutions address-

ing anti-tobacco legislation, the liability of physicians treating Medicare and Medicaid patients; OSMA members holding more than one general OSMA office at a time; federal legislation on determination of the market value of a physician's practice; state legislation to regulating PPOs; public education about seatbelts, bicycle helmets, and HIV protection; and unfair or punitive actions by third parties and licensing boards against physicians in recognized recovery programs.

Topics dealt with in rejected resolutions included retired physicians holding elective positions in the OSMA, the reinstitution of CME requirements for OSMA membership and state licensure, and Oklahoma's status as a unified state.

ADOPTED

Resolution 4—Support of Hospice in Health Benefits Programs. Urges the AMA to support inclusion of hospice care in any health benefits program.

Resolution 5—Strengthening of Anti-Tobacco Legislation. Resolves to seek from the Oklahoma Legislature action that would allow Oklahoma cities to enact anti-tobacco legislation stronger than current state law.

Resolution 6—Initiative Petition to Seek Ban on Tobacco Use in All Public Places. Requires OSMA action with other groups to organize an initiative petition effort seeking a ban on tobacco use in all public places.

Resolution 7—Scrupulous Enforcement of the Prohibition on the Sale of Tobacco Products to Minors. Encourages tobacco retailers to strictly observe the prohibition on sale of tobacco products to minors.

Resolution 9—Governor's Health Care Reform. Supports the concept that physicians, through their elected representatives and voluntary organizations, be actively involved in the planning, implementation, and operations of any Oklahoma health care authority.



Dr. Jay Gregory is the OSMA's new president-elect.

Resolution 12—Professional Liability Under Medicare. Asks that the U.S. Congress be petitioned to place the care and treatment of Medicare patients under the protection of the Federal Tort Claims Act, thus giving physicians some protection from this increased liability.

Resolution 13—Professional Liability Under Medicaid. Asks to have the care and treatment of Medicaid patients brought under the protection of the Oklahoma Tort Claims Act in order to provide physicians with some amount of liability protection.



Marion Howard, PhD, speaks at the luncheon sponsored by OSMA's Women in Medicine.

Resolution 14—Licensure Board Rules on Communicable Diseases. Urges the Oklahoma Board of Medical Licensure and Supervision to accept the state health department's Health Advisory Committee for Infected Health Care Workers as the instrument for assessing, monitoring, and making recommendations regarding practice restriction on HIV-infected health care workers, and specifies that involvement of the licensure board be initiated in such cases only after a request for intervention from the Advisory Committee.

Substitute Resolution 18—OSMA Elected Positions. States that OSMA members may not hold more than one OSMA general office, elected or appointed. If a member holds a general office, he or she may also be a member of the AMA delegation or a member of the PLICO Board, but not both. An exception is made for the president of the association, who serves as a voting member of the PLICO Board of Directors.



Oklahoma City attorney Andy Coats received a Presidential Citation from Dr. Funnell.

Resolution 20—Market Value of Physician Practices. Asks the AMA to seek immediate federal legislation to ensure that all assets of a physician's practice, both tangible and intangible, be used in determining the market value of that practice.

Resolution 21—PPO Participating Physician Fair Hearings. Seeks legislation requiring all PPOs and managed care organizations in Oklahoma to open their provider contracting to any interested and qualified physician, write a "fair hearing" provision into their participating provider contracts, and submit to the regulatory authority of an appropriate state agency.

Late Resolution 22—Bicycle Helmets. Involves

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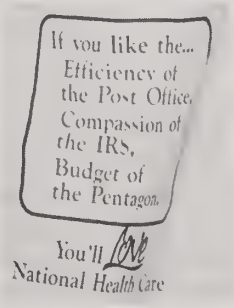
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Resolutions *(continued)*

the OSMA in assisting the state health department in educating the public about the use of bicycle helmets, particularly in children, and in drafting legislation regarding the use of bicycle helmets.

Late Resolution 23—Seat Belt Usage. Commits the OSMA to drafting and supporting legislation to strengthen the seat belt law, extend it to all ages and to passengers in both the front and back seats, and allow primary enforcement by appropriate officials.

Late Resolution 24—Physician Discrimination. Opposes the punitive and indiscriminate action of insurance companies and managed care programs toward physicians in recovery; seeks fair and equitable solutions to the actions of insurance companies, managed care programs, and the state board of licensure against physicians in recognized recovery programs; and opposes punitive and indiscriminate actions by third parties and licensing boards toward such physicians.



An exhibitor's free T-shirts spoke volumes.

Late Resolution 25—Reporting of Maternal Deaths. Encourages all physicians to report maternal deaths to the Maternal Mortality Committee and strongly encourages autopsies in the event of a maternal death for the purpose of advancing medical knowledge.

Late Resolution 26—Physician Ownership. Reminds physicians who currently have investment in facilities to which they refer patients that current law and medical ethics require full disclosure of that involvement to avoid any real or perceived exploitation of patients.

Late Resolution 28—Health Insurance Clarification. Asks the State Insurance Commissioner to require insurance providers to identify and clarify the definition of usual and customary fees.

Adopted As Amended

Resolution 8—Environmental Tobacco Smoke. Declares that environmental tobacco smoke is a major health problem and requests that OSHA and appropriate national and state organizations adopt regulations to eliminate it in the work place.

Resolution 10—OSMA Managed Care Team. Provides for the creation of a managed care team of Oklahoma physician-oriented attorneys and consultants to work with OSMA members in evaluating, developing, and conducting negotiations for managed care plans, including possible physician-owned or -controlled managed care plans, and asks the OSMA to petition the AMA to provide the services of its Managed Care Team to Oklahoma and other unified states at a 50% discount.

Resolution 3—Unconventional Medical Care in the U.S. Condemns recognition and endorsement of non-scientific paltry.

Resolution 15—AIDS and Athletics. Urges Oklahomans to learn more about HIV and the real risks of becoming infected with HIV and endorses the view that HIV-infected athletes be allowed to compete in competitive sports at all levels of contest when proper preventive and precautionary guidelines are followed.

Resolution 16—Economic Credentialing. Opposes the use of criteria not related to quality of care in determining an individual physician's qualifications for the granting or renewal of medical staff membership or privileges, and directs OSMA trustees to ask for the assistance of the AMA General Counsel's office to evaluate any case involving an Oklahoma doctor and the issue of "economic credentialing."

Late Resolution 27—Policy Statement—Oklahoma State Board of Health. Presents without comment a policy statement from the Board of Health supporting both public and private health care efforts in Oklahoma and commends the board for the smooth transition of leadership from Commissioner Leavitt to Commissioner Peace.

Not Adopted

Resolution 1—Continuing Medical Education. Asked the House of Delegates to appoint a task force to study and make recommendations regarding the reinstitution of CME requirements for both OSMA membership and state licensure.

Resolution 2—Deunification. Asked OSMA to rescind its unified status with the AMA.

Resolution 11—Good Samaritan Act and Medicare/Medicaid. Asked that OSMA seek to have unbilled care and treatment of patients brought under the protection of the Oklahoma Good Samaritan Act.

Resolution 17—Retired Physicians. Would have made retired physicians ineligible for elected positions with the OSMA and the AMA.

Resolution 19—Political Action Committees. Would have prevented the AMA, its constituent state and county organizations, and their elected officers from engaging in political activity in the name of those organizations, but did not bar any members or officers from engaging in political activities an individuals. ❑

President Jim Funnell addresses House of Delegates

Thank you Mr. Speaker, Mrs. Vice Speaker, officers, delegates, and colleagues.

In describing this past year as your president and looking to what the future has in store for medicine, I felt the words of Charles Dickens, in the novel *A Tale of Two Cities,* most appropriate: "It was the best of times. It was the worst of times."

Today, it certainly is the best of times for the medical profession because we can do more for our patients than ever before. American medicine stands today as the finest in the world. The best and brightest students from foreign lands come here to train. The art and science of medicine that we practice today add years to our life spans, and, more importantly, add quality to those extra years medicine gives us. Only fifty years ago the cures and healings that you and I are privileged to effect every day would have been considered miraculous. Now they are routine.

But it is also equally true that these are the worst of times for our profession. The golden age of medicine when the physician was the absolute captain of the ship is gone forever. The business of medicine has made the practice of medicine a nightmare for practicing physicians. We are drowning in a costly sea of rules, regulations, bureaucracy, and red tape. Every clinical action we take is scrutinized by the government, insurance companies, and, all too often, lawyers.

While it is the best of times for our patients clinically, it is the worst of times for many of them, particularly those who are uninsured. Patients as well as physicians are frustrated with the bureaucracy of medicine, and especially the cost.

As we have all seen this year, the public is demanding change in the health care system. They really don't know what kind of change they want, but they want change; and this, be assured, is coming.

In my address one year ago, I said American medicine is at the crossroads. If we project the worst of times ahead, what do we see? We see a world where physician is pitted against physician, specialty against specialty. But, like every coin, there is another side.

What if we project the best of times? It is possible to see a world where an ample supply of primary care physicians is finally given the respect—and reimbursement—they deserve. We see a world of less paperwork and hassle. We see a world where we physicians are free to police ourselves and get rid of the few rotten apples. We see a world where only true malpractice ends up in the courthouse. Best of all, we see a world where physicians can do what they do the best, look out for the health and best interests of their patients without undue interference or scrutiny.



Dr. Funnell

To borrow a title from another English author, Aldous Huxley, is it possible to get to this "Brave New World"? I think it is, because change brings with it opportunity. But there are conditions to be met if we are going to get there. First, we must be a part of the reform process. Burying our heads in the sand or being inflexible will only produce the nightmare of the world we described earlier. Medicine must be creative and open to change. Most important of all, *we must remain united.* Our enemies want to divide and conquer us. We must not let that happen. Now, more than ever, we need organized medicine—our county societies, our specialty societies, the OSMA, and the AMA. We must make sure that they all work together, and we must work together.

If we stay united and remain a part of the health care reform process, our opinions will be heard. While there is no question tomorrow's medicine will be different, there is no reason to believe that it will not be better.

My year as your president has been both enjoyable and exciting. I assure you that the OSMA is respected and listened to in Washington, D.C., as well as at the State Capitol in Oklahoma City. I will share with you something that was a revelation to me during my trips representing you in Washington. I found that our government is being run by yuppies or dings. The aides to most congressmen, both medical and others, are recent college graduates—most from Eastern liberal universities—only one, two, or at most three years out of school. I assure you they are all smart, but at my age, I think experience may be a lot more important and practical than book learnin' alone.

Your OSMA has accomplished many things this year. The OSMA's finances are in good order. The employee pension plan has been redesigned. Oklahoma legislators consistently seek the OSMA's input on health related issues, particularly health care reform.

We have also moved quickly and decisively to ad-

dress the changes that may alter the way we practice medicine.

I have appointed an Ad Hoc Committee on Managed Care with Dr. Joe Crosthwait as chair. The committee will make recommendations on how the OSMA can best prepare and organize physicians to survive and prosper in the new medical environment.

All the health care reformers talk about basic benefit packages. When they talk about basic benefits, they talk in terms of cost containment. When physicians talk about basic benefits, they talk about what is best for their patients. To ensure that our patients are not short-changed by insurance companies or bureaucrats, I have created an OSMA committee to make recommendations on what physicians think should be in any basic benefit packages so our patients will not suffer.

House Bill 1573 and Senate Bill 76 would create an Oklahoma Health Authority and drastically change the way the medical program functions. We have another ad hoc committee studying these bills and Oklahoma health care reform.

I am pleased to report that Dr. Lance Miller will continue these committees during his tenure.

Rest assured the OSMA—and that means you—is a major player in the high stakes game of health care reform.

Finally, I am pleased with our organization's vitality. While I'm sure every candidate for an OSMA office or the PLICO Board would like to be unopposed, the competition for offices shows the interest you have in your association and your profession. While some will get more votes than others, there will be no losers in these elections. This dedication to their profession makes all of our candidates winners.

Billy Dotter gave the society reins to me in excellent condition one year ago. As I turn the reins of the OSMA over to the very capable hands of Dr. Lance Miller, I offer him my support and best wishes. Lance, call me any time I may be of service in any way.

Next I want to say a special thanks to a professional staff second to none—David, Ed, Mike, Lyle, Robert, Claudia, and the support staff headed by Susan and all the women who keep us headed in the right direction. In my year, I have not asked for a single thing that was not quickly and efficiently done.

Finally, I want to thank you, the wonderful physicians in the great state of Oklahoma, for allowing me to serve as your president. It has been a unique honor and privilege that I will never forget. So to end where we began, I can honestly say to you that for me, the past year has been the very best of times. Thank you.

G. Lance Miller steps aboard as new OSMA president

Thank you Mr. Speaker, Madam Vice Speaker, officers, delegates, and colleagues.

Several years ago there was a very popular and very funny movie called *Airplane*. For those of you who didn't see it, the film spoofed air disaster movies and contained the character of a befuddled, substance-abusing air traffic controller who, as the disaster grew, became more addled and out of control and would utter such lines as: "Boy, did I pick the wrong year to give up smoking!" or "Boy, did I pick the wrong year to give up drinking!" With what's going on in medicine, I sometimes find myself thinking "Boy, did I pick the wrong year to become president of the OSMA!"



New OSMA President Lance Miller (l) talks with AMA Executive VP James S. Todd.

Actually, this is a good year to be OSMA president, because medicine faces more challenges now than ever before. And where there are challenges, there are opportunities. Because of the magnitude of the challenges, this will be a year of unprecedented opportunity for physicians to shape the future of our health care delivery system by telling the politicians and the public what's right about medicine.

What do I—we—want to tell the public about medicine? I want to tell people that I'm proud to be a physician and that I honor and respect my profession. Rather than a profession, we share a vocation, because next to the clergy, there is no more special calling than the calling to heal.

I want to tell people that we have the greatest health care system in the world and physicians are the only true advocates for patients.

I want to tell people that physicians believe that health care reform is necessary, but that any reform

(continued)

Dr. Miller's address *(continued)*

efforts that do not include physician input are unacceptable.

I want to tell people whose only answer to cost containment is cutting physician reimbursement because they say we make too much money that I worked and sacrificed long and hard to get to where I am today and I provide a special service that patients obviously value very highly.

I want to tell people that physicians need regulatory relief to once again be able to police our profession and rid it of the few fee gougers and charlatans who disgrace us all.

I want to tell people physicians will gladly volunteer their time to help those in need if there was some assurance that we would not be sued for our charity.

I want to tell people that physicians—particularly those in rural areas—are small business men and women who are an integral and often vital part of their community's economy.

This year will also provide perhaps the best opportunity ever to bring all physicians in this state together in uniting to strive for a common goal-not just a few of us doing the necessary work, but everyone doing his or her share.

Beginning now, this association is placing top priority on bringing this goal of unity to fruition. I am open to any suggestions, from anyone, that will allow us to gain the attention and cooperation of our members.

In keeping with this spirit, your leaders and staff have reviewed all of the association's programs, councils, and committees and have reorganized some and abolished others. We have done this in order to free ourselves to tackle new and innovative programs that we are convinced are essential to the success of this organization and to the well-being of every physician member.

The flagship of these new programs is called IMPACT. This program will greatly enhance our political influence and of all the new programs will offer each member the greatest opportunity to actually be proactive in determining his/her future. IMPACT is a bold step and will require an immense amount of energy and effort to fully develop and above all will require the approval and acceptance of all members of this association.

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Dr. Miller's address *(continued)*

During the coming year, we will be asking each county society to turn out for a briefing on this program, and I hope you, as the leaders of your societies, will encourage your colleagues to attend. A few years ago a prominent state senator told an acquaintance of mine, "If the doctors ever get organized and figure out how the game is played, they will be an unbeatable political force." My fellow physicians, that is exactly what we can do with IMPACT.

Among the many other programs we will initiate this year are study activities for a formal contract evaluation service and a contract negotiation service. In this age of managed competition, we are and increasingly will be faced with the burden of evaluating and negotiating complex contracts. Few of us are qualified to perform these tasks, and the consequences to each of us can be onerous. Our goal is to determine whether the association can help relieve its members of these burdens.

We will be evaluating a public service educational effort. Physicians have for years been saddled with an unfair image problem, and perhaps we would serve our members well by revitalizing our public relations efforts of a few years ago. More importantly, I feel, is an effort to educate the Oklahoma people about who really is responsible for the changes in health care (such as rationing) which are just down the road. If we don't do this, you know and I know the politicians will be happy to let us take the blame. After all, we are the ones who will be caught squarely between the average American's unreasonably high expectations and the calculating, cost-cutting motivation of the policymakers.

We will be initiating several other efforts to increase member participation. We will hold regular leadership conferences, and I encourage you to attend and to encourage your colleagues at home to attend.

Dr. Jay Gregory has agreed to chair an ad hoc committee to study the feasibility of developing a state-of-the-art communications system to allow members to participate in council and committee activities from home or close to home. This undoubtedly would be an expensive proposition, but also undoubtedly would allow many more members to participate in association business and decision making. It is not inconceivable that in some instances our members could attend important meetings while taking calls at home.

There are a number of other services or programs that we will be exploring in the coming months. The possibilities of expanding our scientific educational programs at this meeting, of adding recreational activities, either at this meeting or at other times, and of expanding executive services to specialty societies.

Finally, we are exploring the feasibility of the association becoming an active and perhaps major player in one or all spheres of the new health system (whatever form it turns out to be). Your leaders are awaiting the recommendations of several ad hoc committees studying these issues.

I hope it is obvious that your leaders have taken the steps we envision as necessary to position this organization to be able to provide the services and programs that will most benefit its members during the potentially difficult times ahead.

I encourage your thoughts and recommendations concerning other services or programs that we may have failed to perceive.

If we in the house of medicine have planned appropriately and if we have the ability to carry out those plans with intelligence and energy, then each of us can concentrate on what we do best—provide the best medical care for Oklahomans the world has ever known. Thank you.

OU alums hold annual awards dinner during OSMA meeting

Two physicians and a U.S. Senator were honored by the University of Oklahoma College of Medicine Alumni Association at its annual dinner April 23 at Tulsa's Adam's Mark Hotel.

Recipients were honored for their guidance and leadership in the advancement of the medical profession.

John R. Bozalis, MD, Oklahoma City allergist and clinical professor of medicine at the OU Health Sciences Center, was named Physician of the Year—Private Practice, and Thomas L. Whitsett, professor of medicine and pharmacology at OUHSC, was named Physician of the Year—Academic Medicine. Senator Don Nickles received the Amicus Medicinae (Friend of Medicine) Award.

Dr. Bozalis has been in private practice at the Oklahoma Allergy Clinic in Oklahoma City since 1973 and is on the courtesy staff of most metro area hospitals. He received his medical degree from OU in 1965.

Dr. Whitsett, a Tulsa native, is known for his liposome research. Currently he is collaborating with chemical engineers at OU's Norman campus to develop a technique that uses liposomes to dissolve blood clots. He joined the OUHSC staff as an assistant professor of medicine.

Worth Repeating

'Managing' managed care: How to find the help you need in a new environment

The following article first appeared in the May 1993 issue of the American Medical Association's Medical Staff Legal Advisor.

Physicians might view the current national fixation on managed care with a measure of skepticism, relief, and fear. Skepticism because physicians have always been faced with the challenge of how best to manage their patients' care. Relief because managing care has often been difficult, if not impossible, in an environment that lacked internal or external coordination. A new environment in which physicians are truly empowered to manage their patients' care—rather than being "managed" by multiple, removed entities with differing standards of "appropriate" medical care—holds the promise of improved clinical outcomes, enhanced efficiency, increased patient satisfaction, and reduced hassle factor.

Skepticism and relief, however, are probably overshadowed by fear—fear that the seeming frenetic pace of evolution to managed care may result in ill-fashioned solutions or may leave some physicians without options.

Health reform jargon alone is enough to overwhelm the average physician, who must attempt to track reform developments—local and national, governmental and private—after a twelve-plus hour day of patient care. Local, private developments are occurring at a faster rate than governmental developments as private companies directly contract with provider groups, physicians establish clinics to compete with hospitals, hospitals seek to acquire physician practices, and hospitals and their medical staffs explore opportunities for collaboration. (See the January 1991 issue of *Medical Staff Legal Advisor* for an extensive discussion of ongoing provider efforts to integrate, collaborate and compete.)

There is significant state reform activity in Minnesota, Florida, and Vermont. Governor Cuomo has just announced his reform plan for New York State, and the National Governors' Association reports that governors in 23 states have identified health system reform as their number one priority. Federal activity continues at a fevered pitch. Although mandated federal or state reform will heighten the current impact of managed care and health system restructuring, these developments are progressing rapidly and will continue to do so regardless of whether or when mandated reform occurs.

The rapidly changing environment is causing the American Medical Association (AMA) members to confront critically important decisions that will affect how they practice medicine in the future. AMA members are asking whether they should join a physician/hospital organization (PHO) or form a clinic without walls. Some members have been told that their entire medical staff must agree to become employees or be removed from the medical staff. Others are asking how they can take the initiative in forming physician-driven delivery models. The common denominator among physicians in all these categories is a palpable sense of urgency to learn more about managed care, how it will affect them, and how they should respond.

The AMA has developed a managed care educational program to meet this need. "Medicine in Transition: Managing Change in a New Environment" is an extensive program designed to educate AMA members about managed care and its impact on their practice. Once informed, physicians will be able to make educated choices about the options available to them and control their professional destiny. "Medicine in Transition" has five components. First, beginning in June, there will be a series of books and videotapes available that provide practical information about managed care. This series will introduce new items on a monthly basis, and will provide helpful information to all physicians regardless of their current familiarity with managed care.

Second, American Medical Television (AMT) will broadcast managed care educational programs including personal interviews with physicians who have excelled in the managed care environment and national manage care experts.

Third, the AMA is creating a national network of legal and business managed care experts that will stand ready to provide affordable "hands on" services to AMA members as they respond to managed care. The network responds to members' need to identify physician-friendly advocates easily and quickly. Network participants will be credentialed by a panel of national experts to ensure they have substantive expertise and understand the physician's perspective. The network will also include physicians who will provide "peer-to-peer" consultations about how they adjusted to and prospered in the managed care environment. "Peer-to-peer" consultations will allow members to avoid the

pitfalls that others have overcome and will stimulate creative solutions. The network is an AMA "member only" benefit and will be operational by July.

Fourth, the AMA is developing a series of managed care workshops that can be taken around the country. Like the written materials and AMT programming, the workshops will emphasize practical approaches to the challenges of managed care. A portion of the first workshop will be showcased on June 11 at the meeting of the AMA's Hospital Medical Staff Section. In July, the first workshop will be available to be "taken on the road."

Fifth, the AMA is hiring an in-house attorney with extensive managed care expertise to head up the managed care initiative and assist in development of the next stages of "Medicine in Transition."

It is only natural that the nationwide sense of urgency to find a "quick fix" to the cost and inefficiency of the U.S. health system has filtered down to the physicians who actually drive the system. The impulse for physicians afraid of losing all options is to find an immediate solution such as creating a PHO or a clinic without walls or the next vogue structure. Reflexive reactions, however, have not historically met physicians' needs, as shown by the highly celebrated, but rarely effective, hospital/medical staff organizations of the 1980s

Managed care and health system restructuring offer many opportunities for physicians. There are numerous examples of physician groups that have already seized the initiative in managed care and created opportunities for themselves. These examples show that physician-driven networks and structures are logical and can be extremely successful.

Other physicians have the best chance of finding similar success by taking a measured response to health reform and managed care, one built on education about the environment and the options available to them. "Medicine in Transition: Managing Change in a New Environment" is designed to meet that need by providing AMA members the information necessary to make educated choices about how they will practice medicine in the future.

—Submitted by William O. Coleman, MD
Chairman, OSMA-HMSS

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In Memoriam

1992	
Oliver James Hagg, MD	March 31
Francis Patrick Cawley, MD	April 17
Don Horatio O'Donoghue, MD	April 20
Billie Gene Henley, MD	April 24
Arlo Kenneth Cox, MD	April 27
Charles Victor Williams II, MD	May 1
Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28
1993	
Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd Bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Chester Randall Seba, MD	April 4
Edward Cotter Murray, MD	April 9
William Niebuhr Weaver, MD	April 20
Eric McLain White, MD	April 23
John Franklin DeJarnette, Jr., MD	May 1
Harold Alwin Smith, MD	May 4

Health Department

Heavy metal toxicity

Metals may be the oldest poisons known. Their toxicity has been recognized since at least 370 B.C., when Hippocrates described intestinal colic in a metal worker. This article is the second in a series by the Oklahoma State Department of Health, with support from the Agency for Toxic Substances and Disease Registry. Its purpose is to highlight toxic substances that are commonly found at hazardous waste sites or that pose other environmental or occupational threats.

Metals are chemical elements that cannot be destroyed by burning, biological or chemical degradation, or other treatment. Instead, they remain in the environment where, under the right conditions, they may leach into water supplies, be ingested or respired in dust, or become incorporated into organic compounds and enter the food chain. Heavy metals have been identified at all of the 10 National Priorities List sites designated in Oklahoma for superfund cleanup.

Most toxic metals have multiple organ effects and interfere with specific biochemical and cellular processes. Factors such as age, diet, smoking, alcohol intake, and interactions with other metals influence toxicity, as well as its chemical form. For mercury, nickel, chromium, and other metals that produce hypersensitivity reactions, a person's immune status may also be a variable. In general, children are more susceptible to the effects of heavy metals because they take in more calories per unit body weight and absorb metals more readily from the gastrointestinal tract.

Historically, medical concerns about metals centered around acute or overt health effects. Today, concern is rising over exposure to chronic. low levels of such metals as lead, mercury, cadmium, chromium, and aluminum, which may produce subtle, subclinical health effects. Furthermore, because metals can accumulate and persist in tissues, there is some concern that metals may play a role in promoting or initiating carcinogenesis as well as acting synergistically with organic carcinogens.

Low-level lead toxicity may be one of society's most urgent public health problems, especially among children. today, deteriorating lead paint, dust, soil, and water are the main sources of lead exposure in the U.S. Lead toxicity affects erythrocytes, kidneys, bones, reproductive organs, and the nervous system, which results in neurological deficits and lowered intelligence in children. All effects may occur without overt clinical symptoms. Suggested laboratory tests to evaluate lead intoxication include CBC with peripheral smear, blood lead level, and urinalysis. Chelation therapy is the most common treatment for symptomatic lead poisoning, along with treatment of specific organ effects. Chelation therapy is not always successful because of a high rate of re-intoxication. Therefore, treatment must also include identification and control of lead sources, and education to prevent repoisoning.

Another metal of concern is arsenic. Acute poisoning form arsenic exposure can result in cardiac, pulmonary, dermatologic, gastrointestinal, neurologic, and liver damage as well as death. Chronic exposures are associated with skin cancers, peripheral vascular disease, liver injury, and increased lung cancer mortality. Clinical diagnosis of arsenic intoxication is often difficult because both acute and chronic poisoning present a wide spectrum of signs and symptoms, which are largely dependent upon route of exposure, chemical form, dose, and time elapsed since exposure.

Chromium is also found at hazardous waste sites. The target organ of inhaled chromium is the lung; the kidneys, liver, skin, and immune system may also be affected. The most commonly repeated effects of chronic chromium exposure are contact dermatitis, and irritation and ulceration of the nasal mucosa. In most patients with chronic, low-dose exposure, no specific treatment is needed. The mainstay of management is removing the patient from further exposure and relying on the body's naturally rapid urinary and fecal clearance of the metal.

Update on *V. cholerae*—cholera

Elsewhere in this issue of the JOURNAL, two cases of *Vibrio vulnificus* sepsis are reported, along with recommendations for patients in high-risk categories to avoid ingesting raw seafood. Another *Vibrio* species, *Vibrio cholerae,* is the cause of cholera, an acute enteric disease characterized by the sudden onset of profuse watery stools, occasional vomiting, and rapid dehydration. Cholera is highly preventable and easily treated. Although the infection is often mild, severe untreated cases can rapidly progress to shock and death within a few hours.

Unlike *V. vulnificus,* which has the ability to invade the bloodstream without causing gastrointestinal symptoms, *V. cholerae* colonizes the lining of the gut without actually invading any body tissue. Diar-

(continued)

Cholera *(continued)*

rhea is the result of a *Vibrio*-toxin that stimulates secretion of fluid and electrolytes from the small intestine. Fluid loss can be extreme.

Of the 28 known *Vibrio* species, 10 cause disease in humans, 5 of which cause diarrhea, including *V. cholerae.* Moreover, there are two serogroups of *V. cholerae:* "O1" and "non O1." *V. cholerae* non O1 can cause a wide spectrum of diarrheal illness, especially in coastal areas; cases are sporadic and not identified as "cholera." *V. cholerae* serogroup O1, however, causes epidemic "cholera." *V. cholerae* O1 can be further classified into biotypes or strains, of which "ElTor" and "Classical" have produced the seven worldwide epidemics (pandemics) since 1817.

The seventh pandemic began in 1961 when *V. cholerae* O1, biotype ElTor, spread outward from an endemic focus in Indonesia. In January 1991, this pandemic reached Peru. Subsequently, epidemic cholera has spread to nearly every South American and Central American country. It appeared in central Mexico in mid-1991 and has been reported recently in the Mexican states that border Texas.

Of the 24 cases of cholera reported in the United States in 1991, 20 were related to the Latin American epidemic, 16 of which were exposed during travel to South America. In February 1992, 85 passengers on an airplane flight arriving in Los Angeles reported diarrheal illness; 31 of them later were confirmed to have *V. cholerae* O1 infection. The flight originated in Argentina and stopped in Peru before arriving in Los Angeles.

Clinicians should suspect cholera in any persons with severe watery diarrhea, especially in those returning from areas with epidemic cholera or those with a recent history of ingestion of raw seafood. Such persons should have stool samples collected and sent for culture on TCBS agar (the laboratory should be notified that cholera is suspected). Patients with severe disease often lose over 10% of their body weight and need rapid intravenous (IV) rehydration to avoid shock and death; mild cases can be treated with an appropriate oral rehydration solution. Antibiotics that include *V. cholerae* in their spectrum, such as tetracycline, TMP-SMX, or erythromycin, can decrease the duration of illness.

For more information on the *Vibrio* organisms, or to report a suspected or confirmed case of *V. cholerae* O1 or *V. vulnificus* please call the Communicable Diseases Division at the Oklahoma State Department of Health, (405) 271-4060.

85 Years Ago

Report of the Committee on Public Policy and Medical Legislation to the OSMA House of Delegates

...The obstacles that had hitherto been successful in defeating satisfactory medical legislation have been twofold: First, lack of harmony within our own organization; second, opposition of the so-called irregular schools of medicine on the outside. There never has been a time in the history of medicine, nor will there ever be, when any committee, however able or well disposed, will be able to frame a law that will please all of even our own school, to say nothing of the others. This fact would be ever in mind when passing judgment upon the work of this committee, regardless of its personnel. The committee has always, in the past, as now in the present, found this to be the greatest hindrance with which it has had to contend. Able physicians, for whom the members of this committee have the greatest personal regard and respect, have either arrayed themselves openly against them, or "sulked in their tents" when the battle was on, forgetting that mede of loyalty due the men whom they placed on the firing line, and who were not there of their own choice, but by command of the State Association. After years of organization, even here in Oklahoma, and in which work of organization we are sure you will concede that we have done our part, this should not be the case. To these, permit the Committee to suggest that it is, as stated before, impossible for them to compile a law that will suit every one in all of its parts. Such an effort, if one was foolish enough to dream it, would end in a miserable fiasco. Therefore your support should be loyally given to your Committee in the trying time when the fight is on. To these we have to say that you were sadly missed by your bothers out on the firing line—we needed you.

The opposition on the outside has always developed great strength with the ordinary Legislature by simply raising the time-worn battle cry of "Class Legislation."

There has always been a disposition on the part of some very good members of our profession to criticize the Committee because every doctor in the Association was not kept exactly informed relative to every move of the Committee, and also a copy of the proposed law placed in everyone's hands. In reply we will simply call your attention to the fact that there were several reasons why this could not be done. The first,

85 Years Ago *(continued)*

and a very important one, was, that in order to have done so the members of this Committee would have had to devote their whole time to the work and employ a bevy of stenographers. As it was, they devoted over three months on unremitting toil, taken, I know in my own case, mostly out of our hours of rest. Second, on the checkerboard of events, the pieces were being moved rapidly, so that many times twenty-four hours sufficed to change the whole situation....

We regret to report that, while in the beginning the campaign for a better condition of things in the State was opened under such favorable auspices, we find ourselves unable to report any real progress made. The pity of it is that this negative report is not because of an incompetent or venal Legislature, but, rather, let us take the lesson to heart that it is due to our own faults of disunion and insubordination. Let us firmly resolve that this campaign shall be but the preliminary skirmish, the prelude to a grand campaign, when we shall rise high enough and be big enough to appreciate the fact that the only way we can ever hope to realize any real success is to recognize that in this fight there are engaged others who are only too glad to be recognized as allies, and who have proven by the loyalty with which they stood to their agreement and their fidelity in standing up for a measure that we ourselves must recognize as a good one, that they are at least worthy of our confidence.

—A.L. Blesh, Chairman
C.S. Bobo
G.A. Wall
Le Roy Long
E.O. Barker

J Okla State Med Assoc, Vol. 1, No. 1, June 1908.



Deaths

John Franklin DeJarnette, Jr., MD
1923 - 1993

John F. DeJarnette, Jr., MD, of Ponca City, died May 1, 1993. Dr. DeJarnette was born in Ponca City and attended the University of Oklahoma School of Medicine, where he earned his degree in 1948. After completing his postgraduate education in Oklahoma City and Watonga, he moved to Geary, where he had a general practice for three years. In 1953 he entered the U.S. Air Force, serving on active duty until 1955 and attaining the rank of captain. After his discharge, Dr. DeJarnette returned to Ponca City to continue his practice.

Chester Randall Seba, MD
1910 - 1993

OSMA Life Member Chester R. Seba, MD, a retired general practictioner, died April 4, 1993, in Oklahoma City. Born in Bland, Mo., and raised in Leedey, Okla., he attended the University of Oklahoma School of Medicine, graduating in 1938. Both his internship and residency were completed in Oklahoma City. During World War II, Dr. Seba served as a captain in the U.S. Army Medical Corps. After the war, he established a family practice in Oklahoma City.

Harold Alwin Smith, MD
1947 - 1993

Harold A. Smith, MD, a 1978 graduate of the University of Oklahoma College of Medicine, died May 4, 1993. Dr. Smith was a native of Cleveland, Ohio. After completing his internship in Oklahoma City and his residency at the University of Missouri, he returned to Oklahoma in 1983 to establish a urology practice in Claremore.

William Niebuhr Weaver, MD
1908 - 1993

Teaneck, N.J., native William N. Weaver, MD, an OSMA Life Member, died April 20, 1993, in Muskogee. He was graduated from the Tulane University School of Medicine, New Orleans, in 1932. A specialist in internal medicine, he completed his postgraduate training in Jacksonville, Fla., and Charlottesville, Va., where he was a pathology instructor for one year. Upon

completion of his residency, Dr. Weaver moved to Muskogee, where he practiced until his retirement in 1979. During World War II he was a lieutenant colonel in the U.S. Army, serving from 1941 through 1945.

Eric McLain White, MD
1901 - 1993

Clinton native Eric M. White, MD, an OSMA Life Member, died April 23, 1993, in Tulsa. Dr. White was graduated from the University of Oklahoma School of Medicine in 1936 and established his medical practice in Tulsa two years later. In 1942 he joined the U.S. Army Medical Corps, where he served as a captain for four years, including 21 months in the Pacific theater. After the war he returned to Tulsa, where he maintained a general practice until his retirement in 1979. In 1981 he was named a Tulsa County Medical Society Auxiliary Doctor of the Year.

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The OSMA Board of Trustees is scheduled to meet August 22, 1993, November 14, 1993, and February 20, 1994, in Oklahoma City, and April 14, 1994, at Shangri-La Resort. The latter will be held in conjunction with the OSMA Annual Meeting. Board meetings are open to all OSMA members, and President Lance Miller, MD, invites you to attend. Please call in advance so that additional seating can be arranged.

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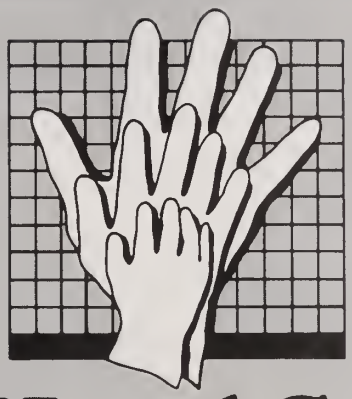
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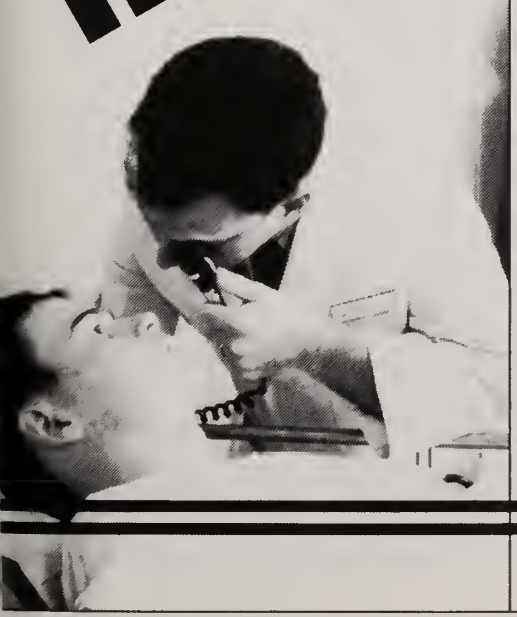
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THE LAST WORD

■ **Five OSMA members were honored recently by** the students in the University of Oklahoma College of Medicine. During ceremonies at the Petroleum Club in Oklahoma City, the following received Aesculapian Awards for having dedicated themselves "both to the teaching of their art, and to the art of their teaching" in the past year: James H. Schmidt, MD, professor of internal medicine, Oklahoma City, was honored by the Class of 1993; Glenn H. Lytle, MD, associate professor and vice chairman of surgery, Tulsa, and John W. Phillips, Jr., MD, clinical associate professor of surgery, Tulsa, by the Class of 1993; and Mark Moseley, MD, resident, Department of Medicine/Pediatrics, Tulsa, by the Class of 1994. Also honored was Ronald C. Elkins, MD, professor and vice head, Department of Surgery, and chief, Section of Thoracic and Cardiovascular Surgery, Oklahoma City, who received the Edgar W. Young Lifetime Achievement Award.

■ **The University of Oklahoma College of Medi**cine was recently touted by *U.S. News & World Report* as the nation's 16th best comprehensive medical school, and reportedly applications are up in the last two years. The university figures also represent an upsurge in out-of-state applicants. Of a total 1,266 applicants in 1993, 831 were from outside the state, according to Associate Dean Nancy Hall. Nationwide, she said, applications to medical schools are expected to reach an all-time high of more than 43,000, after a low in 1988 of 26,721. The OU Health Sciences Center experienced its lowest level of 647 applicants in 1991.

■ **Perry A. Lambird, MD, Oklahoma City patho**logist and chairman of the American Medical Association's Council on Medical Service, testified recently before the U.S. House Ways and Means Health Subcommittee. On April 22, the AMA presented to the subcommittee its version of a standard package of health benefits that should be guaranteed under reform legislation. According to Dr. Lambird's testimony, the package, recently approved by the AMA Board of Trustees, should be provided by all employers to their employees and dependents, and also should be available through state risk pools for otherwise uninsured individuals. The AMA presented its plan at the second hearing of the health subcommittee on standardizing health benefits, during which time over 40 medical groups gave testimony on what should be included in the package.

In its statement, the AMA said its package would cost, on average, $2,700 per employee for individual as well as family coverage. The package "reflects the typical benefits offered in many current health insurance policies," according to the AMA. A key element of the AMA package is preventive health care benefits such as immunizations, smoking cessation programs, periodic examinations, and clinically indicated screening tests, as well as coverage for hospice care, home health care, unlimited outpatient prescription drug benefits, specified organ transplants, skilled nursing facility care, durable medical equipment, and mental health/substance abuse. The package does not include long-term care services or routine dental services.

Stepped-up AMA testimony at task force meetings and congressional hearings is positioning AMA member-physicians as major players in health care reform. It is part of the association's strategy to be involved at all stages of the reform process, presenting issues to the administration and Congress for maximum impact and results.

■ **The AMA has a grassroots strategy to "steer** the proper course for health system reform" once the administration's proposal is unveiled. "We will make the very best use of our communications, grassroots, lobbying, research, and policy and product development for the best possible outcome for patients and physicians," says AMA Executive Vice President James S. Todd, MD. A "call to action" will be issued from the AMA to all physicians. Federation members will be provided with a detailed AMA critique and analysis of the new plan as soon as possible after its release, expected sometime this month.

■ **The AMA's 1993 survey "Public Opinion on** Health Care Issues" indicates the majority of people (80%) would rather pay more for care if they could select personal physicians than pay less and be assigned physicians. Seventy-four percent would pay more to sellect hospitals, and 54% would pay more to ensure local availability of the latest technology.

Only 12% of Americans believe physicians are the single biggest source of health care cost increases. Thirty-four percent named insurance companies, 22% hospitals, and 17% new drugs and advanced technology as the chief causes. Eighty-eight percent of respondents said the AMA should play a role in deciding what kinds of changes should be made in the U.S. health care system.

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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient appnsed of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 6 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. The combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* (1 hour prior to PRAVACHOL), *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL (pravastatin sodium) was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chononic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chononic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallenan degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallenan-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL (pravastatin sodium), it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Intluenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, ano, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

(J4-422A)

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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ABOUT THE COVER

This American bald eagle, our national symbol, is a permanent resident at the nature center near Western Hills Lodge in Sequoyah State Park. Photograph by Dr. Stanley N. Schwartz, Tulsa. Art direction by Graphic Art Center, Oklahoma City.



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Ray V. McIntyre, MD

On Wheezing Insurance

The prevalence of recent medical treatment successes has lulled the medical profession into forgetting that some diseases now have worsening mortality statistics. Despite marvelous improvements in the pharmaceutics and therapies available to the physician, the death rate currently is rising for some diagnoses.

While some of these deteriorating rates are in diagnoses associated with human behavioral foibles such as hedonism and recklessness, some are not. One of the alarming changes we now plainly see is the definite rise in deaths due to bronchial asthma. Despite major pharmaceutical and physical therapy improvements in the acute treatment and long-term management of asthma, reliable medical literature reports clearly signal the asthma death rate to be widely and significantly increasing.

Why is it, in an era when nearly all primary and specialist physicians understand effective asthma treatment, that the death rate and the morbidity statistic for asthma are deteriorating alarmingly? In most diseases, when more effective drugs and therapies are generally used by physicians, death rates and morbidity rates go down and not up.

That the asthma death rate increase is worse than the morbidity rate increase points to treatment access problems as the source of the increase in asthma deaths.

The poignant true story that begins on page 351 in this issue vividly documents a near-fatality due to bronchial asthma. The personal narrative graphically reveals the terrible emotional anxiety of delayed asthma treatment, and also shows a probably cause for the increased asthma death rate, and indirectly points out a significant flaw in the managed care and peer group concept of medical insurance.

Clinically, asthma attacks are precipitated by stressful and often unpredictable events, and patient anxiety is a well-known exacerbation. If the patient's insurance contract includes a threshold control *before* emergency care, or a financial penalty for use of unauthorized sites of service, then asthma mortality will certainly be increased by the insurance procedure. Asthma, like trauma, requires expedited access to medical service to minimize mortality. Imagine a demand to call an insurance agent before calling the fire department to report your house on fire!

Currently, many group insurance contract are negotiated by third parties with a fourth party, and neither the captive patient nor the physician can bargain about the details of coverage. Thus individual medical needs of low statistical probability can be excluded from the contract or "managed" through financial penalty mechanisms. Patient suffering and possible fatalities result.

All peer group insurance contracts are maladaptive to medical progress and experience a time-based deterioration in expense ratios. Insurance contracts that constrict patient/physician contact do limit company expenses, but this ploy simultaneously reduces the frequency of life-saving medical treatment.

Our society needs to develop a medical insurance mechanism that returns personal negotiating responsibility to the individual patient, and changes medical insurance into a resource instead of a barrier to access to medical care.

Ray V. McIntyre, M.D.

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PRESIDENT'S PAGE

G. Lance Miller, MD

That Was Then and This Is Now



Last month this association's delegation and president made the annual sojourn to Chicago to represent Oklahoma physicians at the annual AMA House of Delegates meeting.

Typical of the last few years, an inordinate amount of time and effort were expended on the issue of health care reform. This in addition to the usual busy schedule made for an unusually tiring and hectic trip. More than 100 reports and some 200 resolutions were processed, covering just about any issue important to medicine one could imagine.

The results of those deliberations and debates are important because the end results forge official AMA policy.

I commend every one of our delegates and alternate delegates for their intense effort and the commitment of their precious personal time in our behalf.

We continue to have debate among physicians about the importance of the AMA to the practicing individual. Every year at our state delegates' meeting, someone submits a resolution to deunify.

I cannot agree with that opinion. It is true that until a few years ago there was reason to be unhappy with, even distrustful of, the goals, the direction, and the efficiency of the AMA.

At that time, the leadership was distant and haughty, and clearly had its own agenda.

That was then and this is now.

A few years ago an overdue house cleaning occurred that ushered in a new AMA executive vice president and staff and, more importantly, a re-evaluation of the goals and purposes of the organization. The current administration has proven itself extremely organized and efficient and quite receptive to its membership. The executive vice president, Dr. James Todd in particular, has been very effective and is held in high esteem by national political, business, labor, and other leaders.

It is clear to me that the national house of medicine must have a single, authoritative voice with whom all political and economic entities in the country can deal. We must not and cannot allow each and every specialty organization to speak for and negotiate for its own constituents on important national issues. Such an arrangement would create chaos for us all—just what the politicians would like to see happen. Remember the old cliché "Divided we fall"?

We have already seen examples of several specialty societies favoring different solutions for health care reform. This results in the perception by others that medicine is divided, weak, and impotent.

The argument of the deunifiers is that they have no input into the AMA; therefore the AMA does not speak for them. Wrong!

The AMA gains input from practicing physicians in two ways:

First, the AMA monitors state associations very closely and each state can and does communicate with it regularly. Each of us communicates with the AMA by actively participating in our state association, electing and then communicating with its officers.

Second, each state organization participates in governing the AMA and in setting AMA policies through its own delegation to the AMA House of Delegates.

Invariably those physicians, like myself, who have attended and observed an AMA House of Delegates session, leave with a new appreciation for the organization. Each resolution/issue is debated thoroughly, sometimes heatedly. Every delegate is allowed to speak his/her own mind or that of his/her delegation. The process is painfully democratic.

Not only are the states represented, but each specialty organization, the military medical corps, and others are awarded delegates.

What other organization is so inclusively and democratically qualified to speak for all of us?

What organization was the first to come forward with a comprehensive plan for health care reform? The AMA, in 1990.

What organization broke the band of exclusion of physicians in the Clinton Administration's health care reform deliberations? The AMA, with a march on Washington, March 23-25.

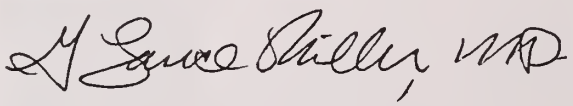
What organization is now regularly meeting with Ira Magaziner and others from the President's task force? The AMA. Information leaked from the task force deliberations strongly suggests that many

(continued)

elements of the plan reflect established policy of the AMA.

What organization already has prepared a grassroots campaign to deal with the Clintons' health care reform proposal when it is finally made public? The AMA.

I urge each of you to pay special attention to the mail you receive from the AMA, particularly over the next few months. It will educate you about what is happening in the health care reform arena and may well, at some point, offer you an opportunity to participate in influencing the final outcome.



SCIENTIFIC

Classification of Autogenous Skull Grafts in Cranial Reconstruction

P. David Hunter, MD; Stanley Pelofsky, MD

A classification of autogenous skull grafts in cranial reconstruction is presented. These include transpositional, sliding, full thickness split, shave, bone dust, and vascular pedicle. The uses of each graft and its advantages and disadvantages are discussed. The location of the defect, the size, and thickness of the skull are variables that must be considered in using these grafts. Many times a combination of grafts is required to provide the best cranial contour.

DUE TO THE RISKS OF DAMAGE TO THE BRAIN, CRANIAL defects create an ever present apprehension in patients and family members. These risks force patients to seek repair of cranial defects as early as possible. Over the years, surgeons have used a number of materials, with autogenous bone grafts becoming the most popular. The uses of rib and iliac bones have been troubled by high reabsorption and morbidity of the donor site.[1,2] Therefore, membranous bone grafts, i.e., autogenous skull grafts, have moved to the forefront because of a high survivability and lower donor site morbidity.[1,2] Although the literature gives a general description of various techniques of reconstruction of the cranium with autogenous bone grafts, no classification exists which outlines the options in an orderly fashion. Therefore, we present a classification for the use of autogenous skull grafts in cranial reconstruction.

Direct correspondence to P. David Hunter, MD, 5300 North Grand, Suite 100, Oklahoma City, OK 73112.

Classification

Transpositional. This type of graft has become the most common calvarial graft used. It was popularized by Tessier and has been described by several authors mostly in facial reconstruction.[4,5] A template of the recipient site is used to outline the graft at the donor site. The borders of the graft are outlined, and the bone around the borders is removed down to the diploic space. The outer table can then be split along the diploic space. The graft is transposed over normal skull to the donor site (Figs. 1, 2).

Advantages of the transposition graft are (1) it can be trimmed to provide a precise fit for the donor defect, allowing for smooth contour of defect; (2) it allows

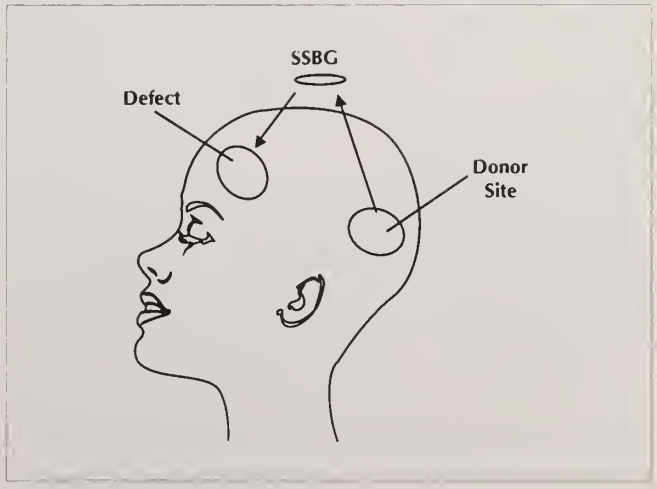


Figure 1. Transpositional graft.

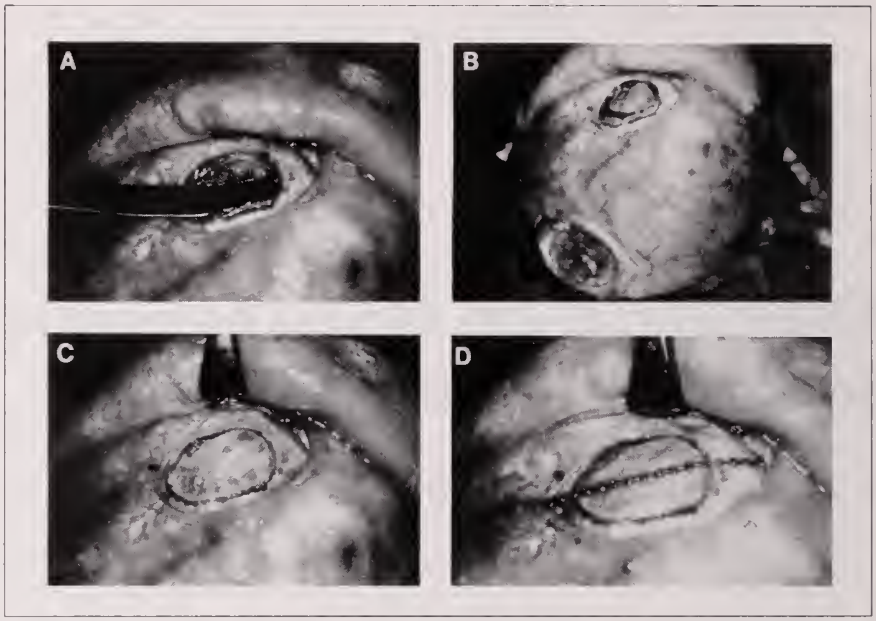


Figure 2A.
Defect shown in frontal bone.

Figure 2B.
Defect top donor site for split skull bone graft (SSPG).

Figure 2C.
Transpositional graft filling defect.

Figure 2D.
Rigid fixation of transpositional graft Luhr micro bone plate and screw.

for an advantageous selection of the donor site; and (3) the bone-to-bone contact obtained by precise fitting allows for solid bony union. Although this has been the most common graft used, it is not without its disadvantages which include (1) contouring of the graft to precisely fit the recipient site can be time consuming and requires multiple attempts; (2) large gaps that heal with a fibrous union will allow posterior migration of bone flap, creating a depression of the cranial contour; (3) membranous bone grafts are brittle, making harvesting of large grafts difficult; and (4) many times multiple grafts must be harvested to fill large defects, making contouring of the defect complicated. Therefore, the main limiting factor in the use of transpositional graft is the size of the defect. Transpositional grafts are generally used for cranial defects in areas covered by non–hair bearing skin. This includes frontal, frontotemporal, and frontoparietal regions. The size of the defect is usually small or medium size (2-6 cm). Defects of the skull base can also be treated with the transpositional graft.

Full Thickness Split. First described in 1890 by Mueller[6] and again by Konig,[7] this type of graft has been used off and on since the early 1900s. More recently Marchac and Renier[8] reported its use in cranioplasties in children, and Guyron et al[9] described the full thickness split in large cranial defects.

The technique of harvesting is begun by removing a full thickness portion of skull either adjacent to the defect or at some distant site. Once removed, the graft is split along the diploic space using either an osteotome or a saw. The inner table is placed into the recipient site and fixed into position using rigid fixation with plate and screws or wire. The outer table is trimmed to fit the donor site, as in the transpositional graft. Once again, fixation is performed as in the recipient site (Figs. 3, 4).

The full thickness split has several advantages. (1) It can be used for large cranial defects. (2) It is easier to split. (3) A donor site can be chosen anywhere on the skull. (4) It can be used on thin skulls.

The major disadvantages include the risk of dural tears during harvesting, longer operating time, and

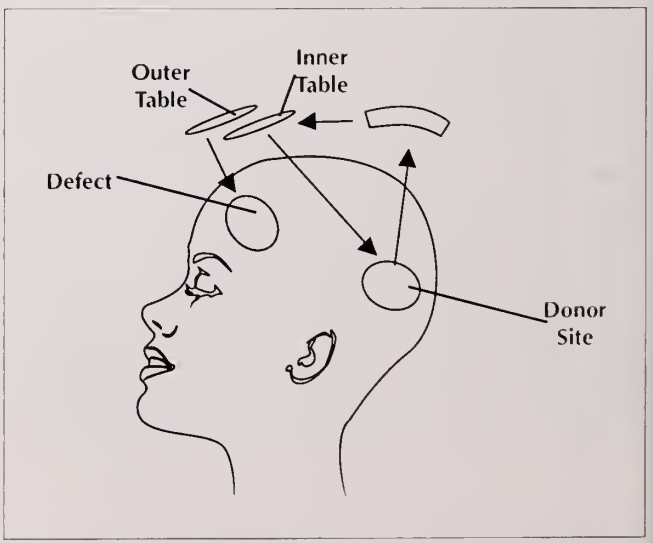


Figure 3. Full thickness split.

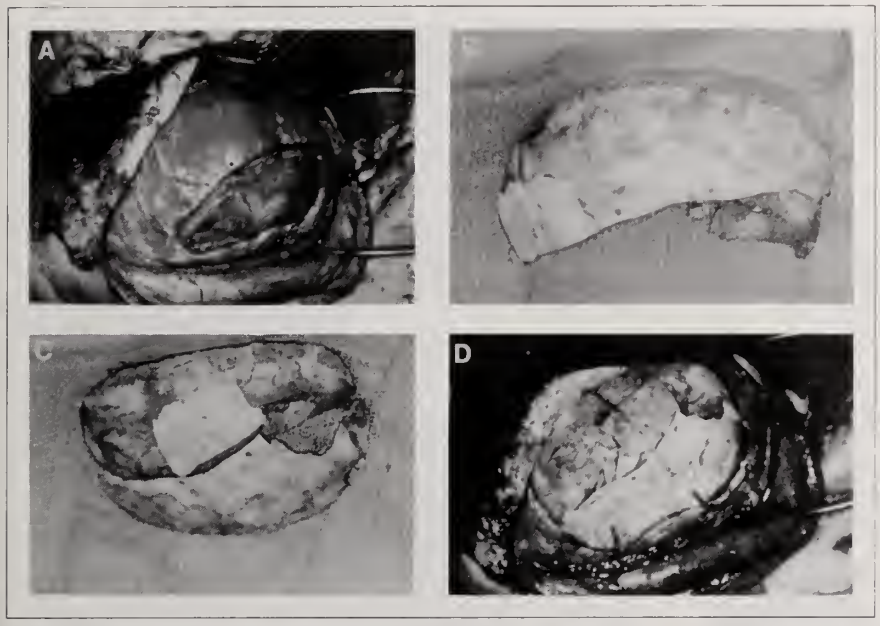


Figure 4A.
Defect seen in parietal occipital area.

Figure 4B.
Full thickness graft superior to defect.

Figure 4C.
Full thickness graft split into two portions.

Figure 4D.
Full thickness graft split covering defect and donor site with micro bone plates for rigid fixation.

two free grafts instead of one. The full thickness split is used for large defects (greater than 6 cm) in the cranium and for thin skulls where splitting with an osteotome is difficult.

Sliding. This technique allows for the use of adjacent bone with an advancement and rotation technique as seen in local skin flaps. The cranium is outlined adjacent to the defect, depending on the geometric shape (Figs. 5, 6). The donor site is generally made larger in one dimension so that when the advancement or rotation of the graft is done, the edges will overlap between the recipient and donor sites. Once outlined, the donor site is cut along the edges, again with a saw or cutting bur. The graft is split in the diploic space, followed by advancing or rotating the bone flap. The overlapping edge allows for better stability of the graft and possibly earlier vascularization through the overlapping diploic space.[10] Rigid fixation with bone plates and screws or wiring can be used.

The sliding cranioplasty offers several advantages. (1) It does not require precise graft size cranial defect. (2) It provides better stabilization with overlapping edges. (3) It takes advantage of all three reossification centers of the skull, i.e., dura, periosteum, and endosteum of diploic space. Its limitations are related to location and size of the cranial defect. As this technique uses adjacent bone, defects occurring in the frontal area may create a defect that can be seen through the overlying skin. Large defects create a problem with splitting the adjacent bone with an osteotome, especially in thin skulls.

Many times, this problem can be reduced by doing a bilateral advancement. It is generally used in any size defect in most locations of the skull. The donor site may require other grafts such as bone dust or shave grafts to achieve the best contour.

Shave. Shave grafts are thin strips of outer table usually harvested with an osteotome (Figs. 7, 8). Jackson et al[4] described their technique of harvesting multiple grafts without leaving a donor defect by the use of a wide osteotome. The shave grafts are used in small defects (2 cm or less) especially in children, but are also used to fill donor sites and to contour graft sites.

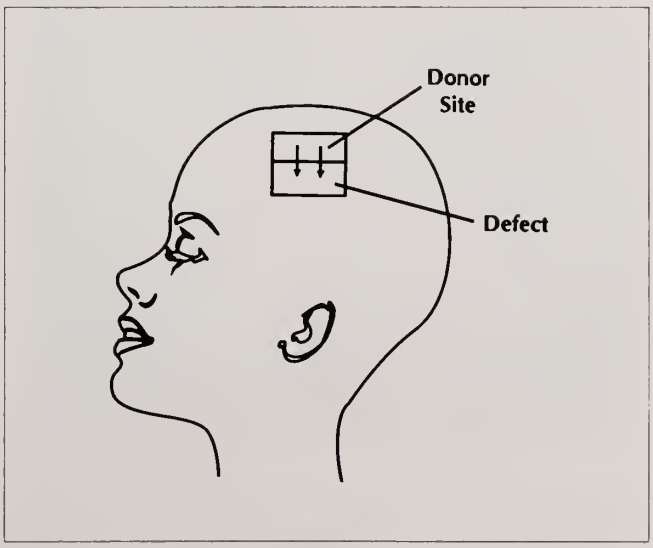


Figure 5. Sliding graft.

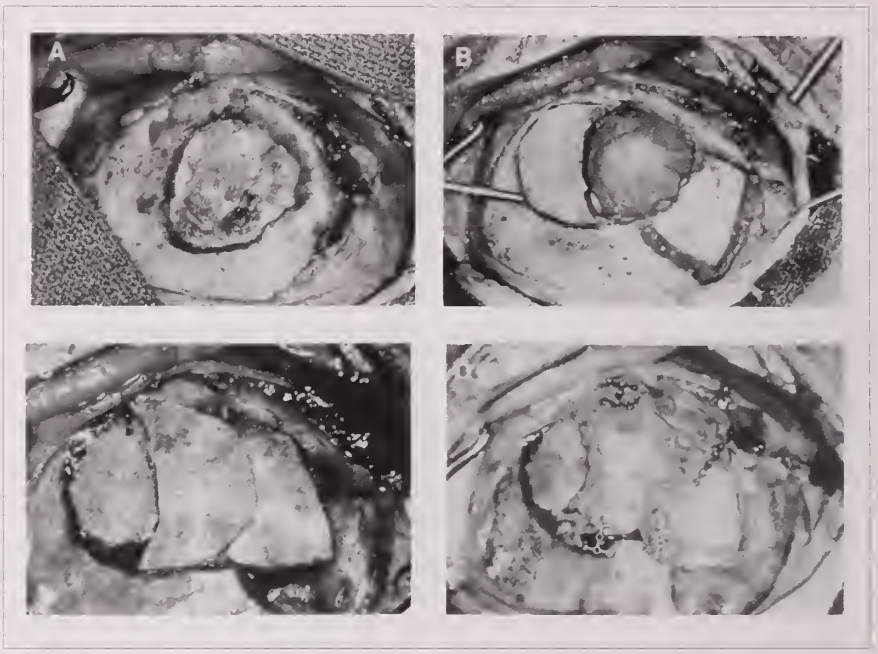


Figure 6A.
Defect in frontoparietal region.
Figure 6B.
Bilateral sliding bone graft cut.
Figure 6C.
Graft rotated and advanced into defect.
Figure 6D.
Rigid fixation with micro bone plates and screws; note contouring with bone dust and shave grafts.

Because of the thinness, it is difficult to affix these grafts to donor sites. Many times rigid fixation can be obtained using a 2 mm or 3 mm microscrew placed through the shave graft and underlying cranium. Super glue can also be used for this purpose.

Bone Dust. Described by several authors,[4,11] this technique of obtaining bone dust by the use of a drill or craniotome has been found to be very useful in contouring of graft sites, both recipient and donor (and for bur holes) (Fig. 9). Also in this classification is bone mill, which is bone chips placed in a grinder (Fig. 10). This produces a particle size larger than the graft harvested by the craniotome or high speed drill, but which still provides a good contour when placed over the defect. It is generally used for contouring of graft sites or for small defects such as bur holes. The survivability of the osteocytes in the bone dust has been questioned. Certainly low speed drills with constant irritation increase the chance that osteocytes will survive. Jackson[4] has reported the use of bone dust in cranial reconstruction to be acceptable. We have used bone dust from high speed drills and found that it provides long-term contouring, but we have no data on the survivability of the osteocytes.

Vascularized Pedicle. The dermal-osteo-periosteal flap as a vascularized bone flap was described by Mueller[6] in the early 1890s, but more recently the vascularized calvarial flap described by McCarthy et al[12] has gained the most popularity. This flap includes in its pedicle the innominate fascia, the deep temporal fascia, and possible galea as blood supplies to the outer table calvarial bone grafts. The major advantage of the vascularized graft is its use in poorly vascularized areas, i.e., radiation or post traumatic scarring. It also is reported to have a better survivability of bone volume and improved growth.[12] The limited range of rotation and sizes of the graft that can be harvested represents a marked disadvantage of its use. Its use in cranial reconstruction has a limited and specialized role.

Discussion

In split skull bone grafts, we are left with a thin donor

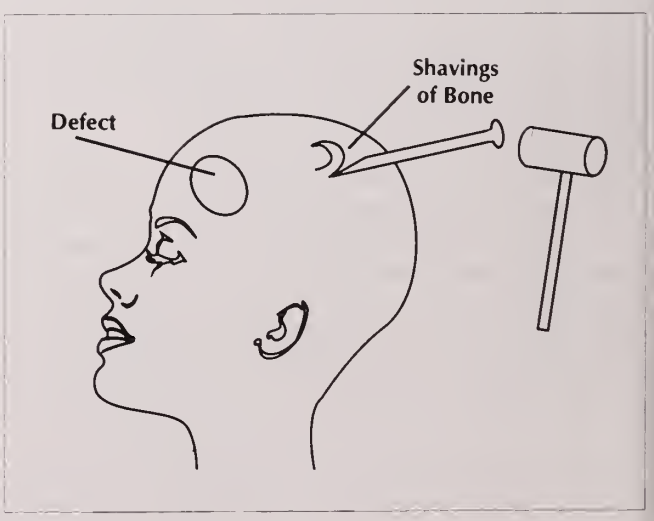


Figure 7. Shave graft.



Figure 8A. Harvesting of shave grafts with osteotome.
Figure 8B. Multiple shaved grafts after harvesting.

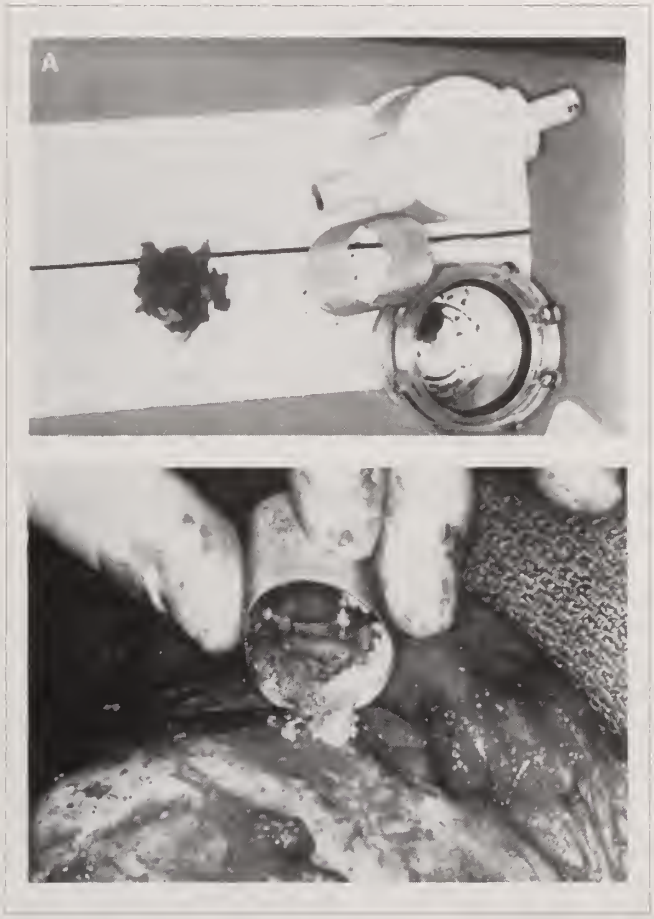


Figure 9A. Bone dust trap used for harvesting bone dust.
Figure 9B. Bone dust used for contouring of cranial defect.



Figure 10A. Bone mill.



Figure 10B. Bone mill used to fill frontal defect.

site. The exact fate of this area is still in question. Reossification of the skull occurs mainly from the dura, but is aided by the endosteum lining the diploic spaces and periosteum over the outer table. It is our belief that all these forces to some degree will replace the outer table. This defect can decreased further by using shave grafts and bone dust to repair the donor site. To better understand the advantages of autogenous skull grafts, we need only look at the complications and morbidity associated with other grafts. Rib and iliac grafts are known for the pain at the donor site and increased pulmonary problems and bleeding. These are further troubled by increased reabsorption.[2] Infection and extrusion have been seen with acrylic implants and with some metallic implants.[13] Autogenous skull grafts present the fewest complications and better survival of the grafts.

The location of the defect, as well as the size and thickness of the skull, must be taken into account when deciding which graft or combination of grafts are to be used in the reconstruction process. It is not uncommon in reconstruction of large cranial defects to use a multitude of graft types. Each type has its own set of characteristics that makes it advantageous, but each also has distinct disadvantages. It is by understanding these graft characteristics that the surgeon gains the versatility needed in reconstructing cranial defects.

Summary

We have presented a classification of autogenous skull grafts in cranial reconstruction: transpositional, sliding, full thickness split, shave, bone dust, and vascular pedicle. The advantages, uses and disadvantages are discussed. It is shown that each type has characteristics that make it the treatment of choice for cranial defects in specific areas. However, a combination of these techniques also can be used in dealing with some cranial defects.

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Diseases Associated with Pet and Wild Birds

Don S. Harper, MD; Stanley N. Schwartz, MD

Exposure to birds can result in human infections that may be difficult to recognize. Immunocompromised individuals are at a greater risk for many of these infections. A history of bird exposure should be sought in patients with unusual infectious syndromes. We provide a description of several of these illnesses along with a comprehensive list of diseases associated with exposure to various species of pet and wild birds.

BIRDS ARE AN IMPORTANT THOUGH INFREQUENT source of diseases in man, especially infections. The incidence of infections from birds may rise in the population of patients immunocompromised by illness or immunosuppressive therapies. We report an unusual avian source for cryptococcosis in an immunosuppressed patient.

Case Report

A 67-year-old woman being treated with glucocorticoids and methotrexate for rheumatoid arthritis began caring for her son's cockatoo. After six weeks of providing feed for the bird, cleaning the cage, and allowing the bird to perch on her wrist as well as fly freely around the house, she developed malaise, fatigue, and depression. Shortly after, she noticed painless subcutaneous nodules over the left popliteal area, left iliac crest, and left wrist. Biopsy of one of the nodules revealed cryptococcal spores. Cryptococcal serum antigen was positive at 1:128. A radiograph of the left wrist revealed a lytic lesion of the distal radius. She underwent surgical debridement of the wrist lesion, and she was given a six-week course of amphotericin B and flucytosine. She had complete resolution of symptoms and healing of the nodules and wrist lesion. The serum cryptococcal antigen returned to negative.

Discussion

Cryptococcal infections are among the most frequent to affect both birds and humans. Humans are relatively resistant to the organism unless they are taking corticosteroids or have Hodgkin's disease, diabetes mellitus, lymphoma, leukemia, sarcoidosis,[1] HIV, or AIDS. The usual environmental source of the infection is the dropping and filth found in the nests of birds, usually pigeons.[1] The inhaled spores cause systemic infection. Generally, birds are not affected by the fungus, but the cryptococcus, which passes through their gut, can remain viable for up to two years.[1] The welcome swallow has had cryptococcus cultured from its nest.[2] We are unaware of any previous case of cryptococcosis in humans following exposure to a cockatoo or any psittacine bird.

Cryptococcus neoformans can occur in many different animals, but pigeons pose the greatest danger to man. Individuals exposed to birds that carry cryptococcus should be encouraged to take appropriate precautions, such as wearing masks during exposure or when hosing down pigeon lofts or chicken coops.[3]

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Other common infections may involve birds. Zoonotic transmission of histoplasmosis usually occurs in a person involved in raising birds (or harvesting bat manure).[3] The fungus is found in the droppings of chickens, pigeons, starlings, and blackbirds.[2] The most commonly implicated bird is the pigeon. To protect persons involved in caring for chickens or pet pigeons, the soil surrounding the habitat of the creatures should be sprayed with water to reduce dust, and masks should be worn when intense exposure is expected.[3]

The distribution of psittacosis is worldwide. Most species of bird can serve as host, and fowl, especially turkeys, have been the source of outbreaks of psittacosis among workers in poultry processing plants. *Chlamydia psittaci* can be excreted from apparently healthy birds. Examples include pigeon, budgerigar, and galah.[2] Transmission of the disease is also reported from parrots, parakeets, pigeons, ducks, cockatiels, and canaries.[1]

Many birds harbor Salmonella serotypes in the gastrointestinal tract.[3] Chickens, canaries, parrots, budgerigars, sparrows, pheasants, fowls, gulls, ducks, and pelicans are among the birds affected. The salmonella bacteria are found in the gut or oviducts of the birds. In the latter case, the birds may lay infected eggs.[2]

Although rare, Newcastle disease is an infection much feared by poultry farmers because of its high mortality rates among fowl. In humans, this myxovirus can cause conjunctivitis, an influenza-like syndrome, a mild encephalitis, or a viral pneumonia. Chickens, turkeys, pheasants, guinea fowl, crows, sparrows, parrots, francolins, cormorants, and gannets have

A Compendium of Diseases Carried by or Induced by Birds

Domestic Birds

Chickens—Influenza A,[4] Newcastle,[2] fleas,[2] cryptosporidia,[5] bed bugs,[2] mites,[2] trematodes,[2] listeria,[1] erysipeloid,[1] anthrax,[2] salmonella,[2,3,7] campylobacter,[2,8,9] leptospirosis,[2] avium tuberculosis,[2] histoplasmosis[2,3,6,10] bird fancier's lung[2,6]

Turkeys—Influenza A,[4] Newcastle,[2] cryptosporidia,[5] ornithosis,[2,6,11] aspergillosis[2]

Guinea fowl—Newcastle[2]

Ducks—Influenza A,[4] arbovirus,[2] chlamydia,[1,11] tape worms,[2] trematodes,[2] salmonella,[2] campylobacter,[6] aspergillosis,[2,7] bird fancier's lung[6]

Geese—Influenza A,[4] arbovirus,[2] cryptosporidia,[5] tapeworm,[2] bird fancier's lung[6]

Migratory Birds

Ducks and geese—See above

Terns—Influenza A[4]

Water Fowls/Gulls

Seabirds—Influenza A,[4] ornithosis,[12] trematodes,[2] salmonella,[2] aspergillosis[7]

Pelicans—Trematodes,[2] salmonella[2]

Passerines/Soft Bills

Starling—Avium tuberculosis,[2] histoplasmosis[2,6,10]

Crow—Newcastle[2]

Blackbirds—Histoplasmosis[2,14]

Blue jay—Arbovirus[13]

Gallinaceous birds—Trichophyta galline[2]

Sparrows—Newcastle,[2] salmonella,[2] arbovirus[7,13]

Swallows—Mites,[2] bed bug,[2] cryptococcus[15]

Psittacines

Budgerigars—Influenza A,[4] poliomyelitis,[2] ornithosis,[2,6] salmonella,[2] bird fancier's lung[2,12]

Cockatiel—Ornithosis[1,16]

Cockatoo—Ornithosis,[6] cryptococcus

Canaries—Ornithosis,[1] salmonella,[2] aspergillosis[2]

Finch—Arbovirus[13]

Love birds—Ornithosis[3]

Parakeets—Ornithosis,[1,3,11,16] avium tuberculosis,[7] bird fancier's lung[2,6]

Parrots—Newcastle,[2] chlamydia,[1,3,11,16,17-20,21] salmonella,[2] avium tuberculosis,[7] bird fancier's lung[12]

Game Birds

Pheasants—Newcastle,[2] arbovirus,[7] salmonella,[2] bird fancier's lung,[7] avium tuberculosis[2]

Columbiform Birds

Dove—Arbovirus,[13] bird fancier's lung[6]

Pigeon—Arbovirus,[13] ornithosis,[1,2,3,6] cryptosporidia,[5] ticks,[2] avium tuberculosis,[2] Histoplasmosis,[1-3] cryptococcus,[1-3,6,10] blastomycosis,[22] aspergillosis,[23] bird fancier's lung,[2,3,6,12]

Exotic Birds

Ostriches—Anthrax[2]

Partridges—Avium tuberculosis[2]

all been identified as sources of infection. Protective clothing, masks, and protective eyewear are recommended for those handling infected birds.[2]

Birds, along with several species of mammals and reptiles, serve as a natural source of cryptosporidia, a parasite that causes nausea, vomiting, abdominal cramps, and watery diarrhea in humans. Cryptosporidiosis occurs more often in immunocompromised patients and may be difficult to isolate and treat effectively. It causes a natural diarrhea in turkeys, chickens, domestic geese, parrots, and peacocks.[5]

Pigeon and budgerigar breeders, poultry farmers, and broiler factory employees are at increased risk for bird fancier's lung, a hypersensitivity reaction. The inhalation of organic material from bird droppings or the inhalation of other avian antigens causes an extrinsic allergic alveolitis characterized by dyspnea, cough, fever, chills, and malaise appearing four to seven hours after exposure. Treatment consists of avoidance or removal of the responsible birds. Irreversible pulmonary fibrosis may result with persistent reexposure.[2,6]

Although no cases of influenza infections being transmitted from birds to human have been reported, all 13H and 9N subtypes of influenza A have been isolated from birds, in most of the possible combinations. Terns were the first birds to have influenza A isolated from cloacal swabs. Almost every major group of the class Aves has been shown to have influenza A infections naturally. Migratory birds such as ducks may be a major route of pandemic spread of these viruses.[4]

Conclusion

Unless a physician deals with zoogenic diseases frequently, diseases related to bird exposure may not be immediately recognized. A carefully obtained medical history including inquiry about exposures to pets and wildlife may help, especially when treating immunocompromised patients with obscure complaints. We provide a compendium of infections and hypersensitivity reactions that may result from exposure to birds.

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Symposium on Antimicrobial Therapy
X. Chloramphenicol, Clindamycin, and Metronidazole

Ronald A. Greenfield, MD

This paper is the tenth in the series begun by Dr. Greenfield in the October 1992 JOURNAL.

IN THIS SEGMENT OF THIS SYMPOSIUM, WE WILL DISCUSS three older antibiotics that are useful primarily, although not exclusively, for treatment of infections caused by anaerobic bacteria: chloramphenicol, clindamycin, and metronidazole. Each agent is relatively unique, and there is little prospect for further development of agents closely related to any of them. For lack of a better organizational scheme, they will be discussed in alphabetical order.

Chloramphenicol

Chloramphenicol (Chloromycetin® and others) was independently isolated from *Streptomyces venezuelae* by workers in Caracas, Venezuela, and at the University of Illinois in the 1940s. It was the first antibiotic whose chemical synthesis was feasible both technically and economically for large scale production. It was quickly recognized to have an extraordinary range of antimicrobial activity. It was released in the U.S. in 1949 and was promptly prescribed very frequently, often in cases where antibacterials were not indicated. Associated with widespread use came the emergence of serious toxicity, most notably fatal aplastic anemia. Since that time, chloramphenicol has been an antimicrobial viewed with disdain by many. Agents that are at least equally effective against anaerobic bacteria have been developed. Chloramphenicol was commonly used for an interval for treatment of infections due to β-lactamase producing *Haemophilus influenzae,* but as we have discussed, various newer β-lactam antibiotics are now considered the therapy of choice for such infections. So chloramphenicol usefulness is now limited, but obviously I believe it is worth remembering.

The antimicrobial action of chloramphenicol is mediated by inhibition of protein synthesis, achieved by binding to the 50S ribosomal subunit of the 70S bacterial ribosome at a locus that prevents attachment of the amino-acid–containing end of the aminoacyl-tRNA to its binding region.[1] Its antimicrobial effect is either bacteriostatic or bactericidal, depending on the organism under consideration. It appears to have bactericidal activity against pneumococci, meningococci, and *H. influenzae;* this accounts for its success in treatment of infections that require bactericidal therapy, for example bacterial meningitis, when due to these organisms.[1] On the other hand, against Enterobacteriaceae, the effect of chloramphenicol is generally bacteriostatic. Resistance to chloramphenicol is due to loss of permeability through the bacterial cell wall or is due to bacterial production of chloramphenicol acyltransferase, a plasmid-mediated enzyme that acetylates chloramphenicol into a microbiologically inert form.[2]

An overview of the in vitro antimicrobial activity of chloramphenicol is presented in Table 1. Chloramphen-

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icol is active against most aerobic Gram-positive bacteria except for methicillin-resistant *Staphylococcus aureus* and Enterococci. Chloramphenicol is active against Neisseria, Haemophilus, and Moraxella. Except for *E. coli,* chloramphenicol has variable activity against the Enterobacteriaceae. Chloramphenicol has virtually no activity against *Pseudomonas aeruginosa* but important activity against *P. pseudomallei.* Chloramphenicol is active against most anaerobic bacteria, be they Gram-positive or Gram-negative. Comparative activity of various antibiotics against *Bacteroides fragilis* is presented in Table 2.[3] Chloramphenicol is also active against Rickettsia.

Chloramphenicol is available as capsules for oral administration, as a suspension (as the palmitate ester), and as a preparation for intravenous administration (as the succinate ester). Chloramphenicol is well absorbed, with peak serum levels after a 1 gm oral dose in adults of approximately 12 µg/ml.[1] The palmitate ester provides a tasteless preparation that is equally well absorbed after de-esterification. Intravenous administration of the succinate ester results in peak serum levels of microbiologically active de-esterified chloramphenicol, about 70% of those achieved by oral administration; that's right, chloramphenicol is one of a few drugs that achieve better serum levels orally than intravenously. Intramuscular administration of chloramphenicol results in erratic absorption and should be avoided. Absorption and metabolism of chloramphenicol in newborns and young children can be quite individualistic; expertise in pediatrics and monitoring of serum levels are generally required in these situations.

Table 1. In Vitro Antimicrobial Activity of Chloramphenicol*

Organism	% Susceptible**
Aerobic Gram-positive bacteria	
Staphylococcus aureus	95
S. aureus (methicillin-resistant)	20
Streptococcus pyogenes	100
Group B streptococci	100
Viridans streptococci	100
*S. pneumoniae****	100
Enterococci	12
Aerobic Gram-negative bacteria	
Neisseria meningitidis	100
N. gonorrhoeae	100
*Haemophilus influenzae****	100
Escherichia coli	95
Klebsiella pneumonia	75
Enterobacter	50
Proteus mirabilis	90
*Salmonella typhosa****	100
Shigella sp.	90
Brucella sp.	100
Serratia marcescens	33
Anaerobic Gram-positive bacteria	
Peptococcus	98
Peptostreptococcus	100
Propionibacterium acnes	100
Clostridium perfringens	100
Anaerobic Gram-negative bacteria	
Bacteroides fragilis	100
B. melaninogenicus	100
Fusobacterium	100
Veillonella	100

*Adapted from Reference 1.
**Organisms with MIC ≤12.5 µg/ml.
***Resistant strains are occasionally encountered.

Chloramphenicol is excreted primarily by hepatic glucuronidation and excretion of the resultant microbiologically inactive form by the kidneys. Only 5% to 10% of the dose is excreted in the urine in microbiologically active form, but this can be enough for treatment of urinary tract infections. Chloramphenicol should be used with caution and at reduced dosage in patients with hepatic insufficiency. Dosage adjustment is generally not required in the presence of renal insufficiency.[1]

Chloramphenicol diffuses well into most body tissue and fluid spaces. This corresponds to the antibiotic's low serum protein binding and high lipid solubility. Cerebrospinal fluid levels approach 50% of serum levels even without inflammation of the meninges. Brain concentrations of the antibiotic may far exceed simultaneous serum concentrations.[1]

Well, so far everything sounds wonderful, but now for discussion of toxicity. Bone marrow toxicity is the major concern. Two types of bone marrow toxicity occur. The first is a dose-dependent predictable reversible bone marrow suppression due to the antibiotic effect on inhibition of protein synthesis. This is manifested by reticulocytopenia, anemia, leukopenia, or thrombocytopenia, and any possible combination thereof. This toxicity can readily be monitored and, to repeat, it is reversible. The more serious toxicity is the aplastic anemia already mentioned. This is best estimated to occur in 1 in 24,500 to 1 in 40,000 individuals who have received chloramphenicol, an incidence about 13 times that in the general population. It is called "idiosyncratic," meaning primarily that it is of unknown etiology and entirely unpredictable. It may occur more commonly after oral therapy but also occurs after parenteral therapy. It is considered fatal. However, in the bone marrow transplantation era this may no longer be entirely true (I don't know of a case treated by bone marrow transplantation). It usually occurs after completion

of a course of therapy, but may occur during therapy in one-quarter of cases.[1]

Other side effects of chloramphenicol therapy include hemolytic anemia in patients with the Mediterranean type of glucose-6-phosphate dehydrogenase deficiency (this usually does not occur with the milder type A deficiency more common in blacks), the gray syndrome in neonates, optic neuritis, and rare hypersensitivity reactions.

Several drug-drug interactions with chloramphenicol are noteworthy. Chloramphenicol prolongs the half-life of phenytoin, warfarin, and sulfonylurea oral hypoglycemic agents. Phenytoin and phenobarbital decrease serum levels of chloramphenicol.

First-line clinical indications for chloramphenicol are now virtually nonexistent. It is useful in patients with rickettsial infection who can not take tetracyclines (50 mg/kg/day in 4 divided doses). It remains a therapy of choice for brain abscess of unknown microbiological definition or with proven in vitro susceptibility (100 mg/kg/d). Although indicated for treatment of salmonellosis, there are multiple classes of antimicrobials with this indication that are better alternatives. It remains an important alternative agent in patients with meningococcal, pneumococcal, or *H. influenzae* meningitis who are intolerant of β-lactam antibiotics (100 mg/kg/d). It is a useful third choice for treatment of infections due to anaerobic bacteria; in most situations, clindamycin or metronidazole are preferable.

Development of antibiotics related to chloramphenicol seems unlikely. Thiamphenicol is a related agent that has been available in Japan and Europe for many years but appears to offer no substantive advantage. Chloramphenicol remains a powerful antibiotic useful in particular situations, with a rare but potentially fatal adverse effect.

Clindamycin

Clindamycin (Cleocin® and others) is a lincosamide antibiotic, specifically it is the 7(S)-chloro-7-deoxy derivative of lincomycin. The parent antibiotic, lincomycin, was isolated from *Streptomyces lincolnensis* first isolated from soil from (I hate to admit it) Lincoln, Nebraska, in 1962. There is now no usefulness of lincomycin and it will not be discussed further. Clindamycin is a derivative of the amino acid L-4-n-propylhygrinic acid attached to a sulfa-containing derivative of an octose. Clindamycin was synthesized in 1966.[4]

Clindamycin, like chloramphenicol, exerts its antimicrobial activity by binding to the 50S ribosomal subunit and inhibiting protein synthesis, primarily by inhibition of the initiation of peptide chain synthesis.[5] Clindamycin also somehow alters the bacterial surface in such a way that phagocytosis and intracellular killing are markedly facilitated.[6] Clindamycin concentrates within phagocytic cells.[7]

Table 2. Comparative In Vitro Activity Against the *Bacteroides fragilis* Group*

Antimicrobial Agent	MIC_{90} (μg/ml)	% Resistant
Cefoxitin	16	16
Cefotetan	128	36
Cefotaxime	>128	53
Cefoperazone	>128	66
Ceftizoxime	128	33
Ceftazidime	>128	16
Piperacillin	>128	16
Ticarcillin-clavulanate	16	1.7
Imipenem	1	0.2
Clindamycin	2	6
Chloramphenicol	8	0
Metronidazole	1	0

Adapted from Reference 3

Resistance to clindamycin can be chromosomal or plasmid-mediated and most commonly involves ribosomal mutation.[2] Gram-positive bacteria, most notably *S. aureus,* have developed resistance during therapy.[8] Plasmid-mediated resistance among *Bacteroides fragilis* does occur and has occurred in epidemic proportions in some institutions.[9] Clindamycin appears to exert a bactericidal effect against Gram-positive bacteria and a bacteriostatic effect against Gram-negative bacilli.

Most strains of staphylococci and streptococci are susceptible to clindamycin. Most methicillin-resistant *S. aureus* are resistant, however. I have relatively commonly observed patients treated with clindamycin and a semisynthetic penicillinase resistant penicillin; this is rarely if ever indicated. It is also important to be aware that clindamycin is virtually devoid of activity against Enterococci. This is an important consideration when clindamycin is used as part of an antimicrobial regimen for polymicrobial intraabdominal infections. Many *Clostridium perfringens* are susceptible to clindamycin; most non-perfringens Clostridia are resistant. Most anaerobic Gram-positive cocci are susceptible. Most anaerobic Gram-negative bacilli are also susceptible, although resistance among the *Bacteroides fragilis* group appears to be increasing (Table 2). Clindamycin is active against *Mycoplasma hominis* but not *M. pneumoniae.* Clindamycin also has important

antimicrobial activity against *Babesia microta, Pneumocystis carinii,* and *Toxoplasma gondii.*[2]

Clindamycin is available in four forms: (1) as capsules of clindamycin hydrochloride, (2) as the tasteless palmitate ester in an oral suspension, (3) as the phosphate ester for parenteral injection, and (4) as suspension, lotion, and gel containing clindamycin phosphate for topical use. The esters of clindamycin are microbiologically inert but rapidly converted to clindamycin.

Clindamycin is well absorbed after oral administration, with bioavailability by this route being approximately 90%. Peak serum levels after oral administration of a 150 to 300 mg oral dose are 3 to 4 μg/ml. Peak serum levels after 900 to 1200 mg doses intramuscularly or intravenously are 11 to 14 μg/ml. Topical preparations result in minimal serum levels. The serum half-life is 2 to 4 hr. For treatment of serious infections with susceptible organisms in adults, the usual dosage is 900 mg intravenously q8h. This dosage is pharmacokinetically, pharmacodynamically, and economically preferred to 600 mg intravenously q6h as initially recommended.[10] In fact, 1200 mg intravenously every 12h may ultimately become preferred, but clinical experience with this regimen is as yet inadequate for such a recommendation. Clindamycin does not reliably achieve therapeutic concentrations in cerebrospinal fluid. Clindamycin is primarily metabolized to its sulfoxide and N-demethyl derivatives by the liver. These metabolites have variable antimicrobial activity and are ultimately excreted in bile and urine. Patients with severe liver dysfunction should generally receive clindamycin dosages reduced by 50%. Although some metabolites do accumulate in patients with renal insufficiency, dosage modification is not required, because no adverse effects of such accumulation have been noted.

The most commonly encountered adverse effect in patients receiving therapy with clindamycin is diarrhea. Two forms of diarrhea occur: one originally called pseudomembranous colitis but now known to be due to *Clostridium difficile* and better called *Clostridium difficile* colitis, and diarrhea not associated with *C. difficile.*[11] The incidence of diarrhea following therapy with clindamycin has been variably reported from 3% to 30% with the incidence of *C. difficile* colitis reported as 0.01% to 10.00%. It appears that diarrhea of either type occurs three to four times more commonly with oral than parenteral therapy. Clindamycin gained a great deal of notoriety for causing *C. difficile* colitis, but it should be noted that most *C. difficile* colitis is associated with β-lactam antibiotic therapy.[11] Less common side effects of clindamycin therapy include transient elevation of hepatocellular enzymes, neutropenia, thrombocytopenia, and neuromuscular blockade. Hypersensitivity reactions to clindamycin are rare.

The major clinical usefulness of clindamycin is, of course, for treatment of anaerobic infections. Clindamycin is frequently used in combination regimens (with other member[s] of the combination directed against aerobic Gram-negative bacilli and/or Enterococci) for treatment of polymicrobial intraabdominal or pelvic infections, in which anaerobes are classically involved. Additionally, it can be argued that clindamycin is the therapy of choice for anaerobic pleuropulmonary infections.[12,13] This is based on the progressive development of β-lactamase–mediated resistance to penicillin by non-fragilis Bacteroides during the past decade. Because of this, the old clinical dictum that penicillin is adequate therapy for anaerobic infections above the diaphragm is no longer correct. Thus clindamycin should also be considered a primary therapeutic choice for anaerobic infections of the head and neck, i.e., contiguous to the oropharyngeal cavity. Clindamycin is a useful alternative agent for treatment of infections due to susceptible staphylococci and streptococci, but should not be used for treatment of staphylococcal endocarditis. Several years ago, I achieved some notoriety by pronouncing at Medical Grand Rounds that *S. aureus* endocarditis should never be treated with any drug that begins with *c;* I stand by that statement still. Occasional methicillin-resistant *S. aureus* are susceptible to clindamycin, and therefore, occasionally clindamycin may be useful for treatment of nonendocarditic methicillin-resistant *S. aureus* infections with established in vitro susceptibility. Clindamycin is useful topically or in low chronic systemic dosage for treatment of severe acne vulgaris. Clindamycin is effective alternative therapy for bacterial vaginosis, administered either orally or topically.[14,15]

There are also some more exotic uses of clindamycin. The combination of clindamycin and quinine (or quinidine) is useful for treatment of chloroquine-resistant *Plasmodium falciparum* malaria and may be useful for treatment of babesiosis.[2] The combination of clindamycin and primaquine is effective alternative therapy for *Pneumocystis carinii* pneumonia in patients with AIDS.[16] Clindamycin and pyrimethamine is an effective alternative therapy for *Toxoplasma gondii* infection in AIDS.[17]

Metronidazole

Metronidazole (Flagyl® and others) is a 5-nitroimidazole antimicrobial agent released in 1959. Its pri-

mary antimicrobial activity is against anaerobic bacteria and protozoa.

There are four steps involved in the antimicrobial action of metronidazole. The first is, obviously enough, entry of the drug into the target cell. This is believed to occur by diffusion equally into all microbial and mammalian cells. The critical step is next: activation by a reduction process. The feature differentiating susceptible from nonsusceptible cells is the presence of a nitroreductase system operative at a very low redox potential. This is mediated by ferredoxin-like electron transport proteins. The next step is cytotoxicity. Some not yet convincingly identified and short-lived reduction product(s) mediate(s) this cytotoxicity: candidates are a nitroso derivative, a nitroso-free radical, and a hydroxylamine derivative. These highly reactive products likely interact in a damaging way with DNA. Finally, there is release of inactive end products, namely acetamide and 2-hydroxyethyl oxamic acid.[18] The effect of metronidazole is generally rapidly bactericidal to susceptible organisms.

Resistance to metronidazole is rarely encountered among organisms that are usually susceptible. Resistance has been shown to be due to decreased permeability of the drug or decreased activity of the nitroreductase enzyme system.

The in vitro antimicrobial activity of metronidazole can be summarized as follows.[2] The tendency is to think of metronidazole and excellent activity against anaerobic bacteria. This generalization needs some modification. Metronidazole has excellent activity against anaerobic Gram-negative bacteria (Table 2, for example); however, its activity against anaerobic Gram-positive bacteria is limited. Its activity against the major pathogenic anaerobic Gram-positive cocci, Peptococcus and Peptostreptococcus, in particular, is limited to about one-half of isolates, and this has important correlates in clinical therapeutics, as we shall see. Similarly, metronidazole has essentially no activity against *Propionibacterium acnes.* Metronidazole also has important activity against three protozoan pathogens: *Entamoeba histolytica, Giardia lamblia,* and *Trichomonas vaginalis.*

Pharmacokinetic properties of metronidazole can be summarized as follows. Metronidazole is essentially completely absorbed after oral or rectal administration (and considerably less expensive); serum levels after a 500 mg dose orally, rectally, or intravenously are 20 to 30 μg/ml. Metronidazole diffuses well into nearly all tissue and fluid spaces, including the central nervous system and cerebrospinal fluid. The serum half-life of metronidazole is approximately 8 hours. Metronidazole is metabolized by the liver to various metabolites, some of which have antimicrobial activity, which are excreted in the urine (60-80%) and feces. Dosage reduction is probably in order for both severe hepatic or renal insufficiencies, although precise recommendations are not available.

There are important drug-drug interactions involving metronidazole.[2] Most notable is a disulfiram (Antabuse®)-like effect with alcohol consumption. All patients treated with metronidazole should be warned of this possibility. Metronidazole potentiates the effect of coumarin anticoagulants. Cimetadine therapy increases metronidazole levels,[19] and may therefore increase the likelihood of central nervous system toxicity. Antacids, barbiturates, and cholestyramine have been reported to decrease the serum concentrations of metronidazole.[2]

The most common adverse effect of metronidazole therapy is nausea, which occurs in approximately 12% of patients.[2] Metronidazole therapy may also be associated with a metallic taste in the mouth (even when administered parenterally), vomiting, diarrhea, epigastric pain, and anorexia. An important toxicity of metronidazole therapy is that involving the nervous system.

Metronidazole should not be used alone for treatment of anaerobic pleuropulmonary infection.

These adverse effects appear to be dose related, and include peripheral neuropathy, ataxia, vertigo, seizures, and headache. A great cloud hanging over metronidazole is its mutagenic, teratogenic, and carcinogenic potential.[20] Metronidazole is mutagenic in the Ames test and is carcinogenic in massive doses in some but not all species of rodents. This likely is due to conversion of the drug in sensitive microorganisms to nitroso compounds with known carcinogenic potential; the key question is whether there is any release of these compounds and exposure of host cells. Nonetheless, after 25 years of clinical use, there is no evidence of human carcinogenicity due to metronidazole.[21,22] Metronidazole should not be used in pregnant or nursing patients. Rare adverse reactions associated with metronidazole therapy include transient neutropenia and allergic cutaneous eruptions.

Let us now discuss the therapeutic indications for metronidazole. Metronidazole is clearly the agent of

choice for infections due to anaerobic Gram-negative bacteria when bactericidal therapy is indicated; for example, treatment of Bacteroides meningitis or endocarditis. Metronidazole is effective therapy for the anaerobic Gram-negative bacillary component of mixed aerobic/anaerobic intraabdominal or pelvic infections. It must be used in combination therapy (with drugs active against aerobic Gram-positive and Gram-negative bacteria) in these polymicrobial infections. There is no evidence of its clinical superiority over drugs that may only exert a bacteriostatic effect in these infections. The usual dosage of metronidazole in these situations is an initial dose of 15 mg/kg followed by 7.5 mg/kg q6h. Metronidazole is a treatment of choice for brain abscess due to susceptible organisms. Because of its limited spectrum of activity, however, it should not be used alone for empiric therapy of brain abscess of undetermined microbial etiology. Metronidazole (250 mg PO or IV q6h for 10 to 14 days) is an alternative regimen for treatment of *C. difficile* colitis; most prefer vancomycin for seriously ill patients.[11] Metronidazole is a component of several treatment regimens under evaluation for therapy of *Helicobacter pylori* gastrointestinal infection.[23] Metronidazole is an effective regimen for treatment of bacterial vaginosis (500 mg PO bid for 7 days or a 2 gm single oral dose).[24] There is a role for metronidazole in the treatment of perineal fistulae due to Crohn's disease.[25] Metronidazole is the therapy of choice for the nonpregnant patient with trichomonal vaginitis (2 gm as a single oral dose is the preferred regimen but 250 mg PO tid for 7 days is also effective).[24] Metronidazole is effective therapy for intestinal and extraintestinal amebiasis. Metronidazole is a treatment of choice for giardiasis (250 mg PO tid for 5 days).[2]

A vaginal gel containing 0.75% metronidazole has recently been released and is approved for treatment of bacterial vaginosis (not trichomonal vaginitis). Because serum metronidazole averages about 2% of oral therapy with this topical therapy, the incidence of gastrointestinal complications is lower. However, this regimen is more expensive and in my experience, women often prefer oral over intravaginal therapy. Another topical formulation of metronidazole is approved for treatment of rosacea.

It is important to emphasize one situation in which metronidazole should *not* be used. Metronidazole should not be used alone for treatment of anaerobic pleuropulmonary infection. Failures in this setting have been amply documented.[26] This likely relates to the limited activity of metronidazole against anaerobic Gram-positive cocci noted above. These data should be extended to treatment of anaerobic infections of the head and neck as well.

That concludes this review of these three older antibiotics with continuing usefulness.

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Laparoscopic Gastropexy As Treatment for Incarcerated and Obstructing Sliding Hiatal Hernia

William C. Jennings, MD

A 78-year-old female presented with a two-month history of dysphagia and upper abdominal discomfort associated with significant weight loss. The patient had a long history of mild episodic reflux; however, during this time it became significantly worse and progressed to vomiting any solid food attempted. Full medical work-up yielded no abnormalities other than the incarcerated hiatal hernia (Fig. 1). Late films documented extremely slow emptying of the proximal gastric pouch with continuous reflux of barium into the esophagus and near total obstruction. After a complete review of medical/surgical options with the patient, she elected to undergo a laparoscopic reduction of this hernia and treatment by gastropexy/gastrostomy. The patient underwent uneventful laparoscopic gastropexy with reduction of the incarcerated hiatal hernia. She was hospitalized three days post operatively. She tolerated clear liquids the day following surgery and was advanced to a regular diet three days after the operation. A post surgical barium swallow demonstrates the intra abdominal position of the stomach (Fig. 2). The gastrostomy tube was clamped before discharge and removed three weeks post operatively in the office. The patient has remained well with no gastrointestinal complaints whatsoever. She has regained her lost weight and is doing well six months following the procedure

Operative Technique

The patient's abdomen was insufflated in a standard fashion through a periumbilical incision which then allowed insertion of a 10 mm trocar for the laparoscope. Two mid-abdominal 5 mm trocars were placed under direct vision on both sides of the midline. The omentum was noted to fill the upper abdomen and the majority of the stomach was in the chest (Fig. 3). The head of the operating table was elevated to aid in reduction of the hernia. The patient simultaneously underwent endoscopy as the stomach was gently reduced from the incarceration. No erosive esophagitis or area of ulceration could be identified. The positioning of the stomach for placement of a percutaneous gastrostomy tube was then accomplished under direct vision to ensure the stomach would not return to the chest (Fig. 4). Care was taken to ensure the gastrostomy was placed without undue tension. The endoscopic and laparoscopic procedures were then terminated in standard fashion and without findings of other abnormality.

Discussion

The role of gastropexy in treatment of symptomatic hiatal hernia has been known many years.[1] Nissen recognized its effectiveness and added his operation for fundoplication in those patients needing permanent relief from esophagitis. He also recognized, as others have, that repair of the sliding hiatal hernia diaphragmatic defect was not critical or even necessary. This is in distinction to other acquired diaphragmatic defects that are felt to need repair of the hernia defect. Nissen's fundoplication and repair of diaphragmatic defects have been reported using laparoscopic techniques.[2,3] The technique of laparoscopic gastrosto-

Direct correspondence to William C. Jennings, MD, 1145 South Utica, Suite 202, Tulsa, OK 74104.



Figure 1. Preoperative upper GI study demonstrating intrathoracic stomach.



Figure 2. Post surgical barium swallow study demonstrating intra-abdominal gastric position.

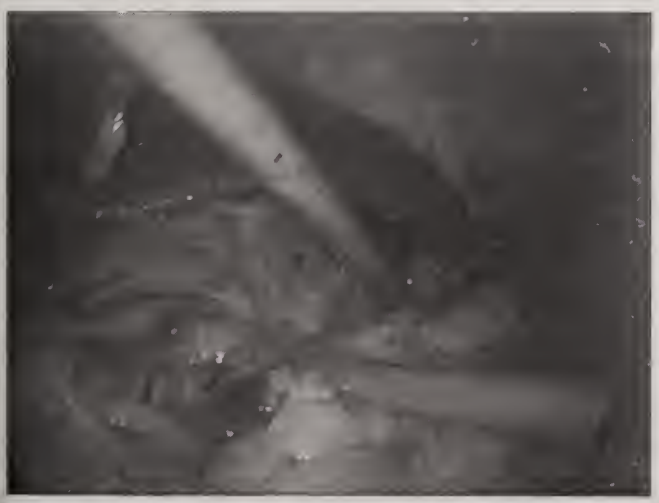


Figure 3. Laparoscopic view of incarcerated stomach with omentum filling the upper abdomen.

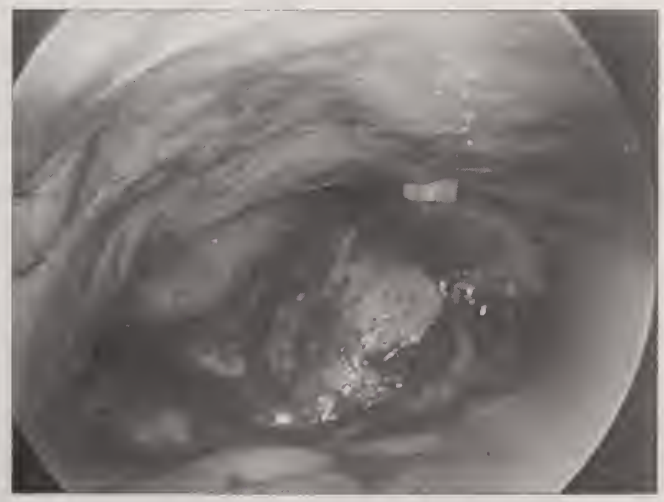


Figure 4. Gastropexy/gastrostomy as stomach is approximated to the anterior abdominal wall.

my has been described recently by Edelman.[4] A gastropexy by tube gastrostomy was empirically chosen over suture techniques as more secure and reliable in addition to the ability to decompress the stomach during the healing period.

As surgeons become increasingly willing to apply laparoscopic techniques to different problems, older and more simple solutions may again present themselves for our consideration.

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The Author

William C. Jennings, MD, is an associate clinical professor of surgery at the University of Oklahoma College of Medicine–Tulsa.

News

OSMA offers full-service pension program through UPAL

The Oklahoma State Medical Association (OSMA) has joined with the Utica Physicians' Association, Ltd., (UPAL) of Tulsa to offer members a full-service pension program.

Dr. William G. Bernhardt, Midwest City, chairman of the OSMA Council on Member Services, said, "The OSMA Pension Program will provide our members with access to six diversified pooled investment funds with money management services provided by top flight, nationally acclaimed managers. By joining UPAL, we bring an established program to our members and do not have to create our own from scratch."

UPAL has provided pension services to Oklahoma physicians since 1986 and currently has assets in excess of $71 million in the program. "We are pleased that OSMA has chosen our organization to provide management of its pension program," says Dr. Donald R. Stout, UPAL president. "Our pension services were developed by physicians for physicians with the goal of providing safe, prudent, management with a variety of investment options.

"We have been very successful because we have chosen nationally recognized experts to assist us. The OSMA Pension Program will provide members with expert counsel, flexibility, and turnkey administration at significant cost savings. Because the program will be independently audited, it will also provide participants safety and peace of mind," Stout concluded.

Through UPAL, the Trust Company of Oklahoma of Tulsa will provide plan and pooled fund trustee services. Employee Benefits Group, Inc., will provide recordkeeping and plan design services. Strategic asset allocation advice will be provided by the Dallas consulting group of Shearson Lehman Brothers.

The six investment fund options include growth equity, small-to-mid-cap equity, international, balanced, fixed, and money market funds.

A comprehensive description of the OSMA Pension Program and all funds is available for review. Interested OSMA members may call toll free, 1-800-259-6262, for more information.

Miller hopes his plan will have impact

OSMA President G. Lance Miller, MD, is looking forward to visiting each county medical society in the state to introduce his new IMPACT program.

IMPACT, Individual Medical Political Action Contributions Together, has been established to organize individual physician support for candidates for political office and is designed to compliment OMPAC, the Oklahoma Medical Political Action Committee. IMPACT originated from a successful pilot project set up by the Tulsa County Medical Society.

Each county society in the state has been asked to appoint physicians to serve as IMPACT coordinators. Dr. Miller's visits will assist in explaining the new program to physicians. Counties wishing to schedule a visit should contact OSMA Associate Director Robert Baker at the OSMA field office, 918-743-9773.

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Home uterine monitoring is not covered by OSEEGIB's plan

Home uterine activity monitoring (HUAM) is not a covered under the state group insurance plan, according to a recent announcement.

Citing a September 1992 report from the American College of Obstetricians and Gynecologists (ACOG), which said "HUAM devices remain investigational and cannot be recommended for routine clinical use," the Oklahoma State and Education Employees Group Insurance Board (OSEEGIB) has decided not to include the monitoring in its benefits package.

The American Medical Association, in 1989, also reviewed HUAM. In their report, entitled "Randomized Controlled Trials of Home Uterine Activity Monitoring: A Review and Critique" [*Obstet Gynecology*, Grimes and Schultz, Vol. 79, No. 1, pp 137-142], the authors said, "The AMA panelists concluded that its effectiveness had not been established. Even for high-risk pregnancies, evidence supporting the use of electronic monitoring is scarce."

OSEEGIB emphasized that case management of high risk pregnancies will continue to be a covered benefit because home health care nursing attention during pregnancy appears to help alleviate premature birth among women at risk.

The board will continue to monitor ACOG's evaluation of HUAM and will review its coverage accordingly.

Physicians with high risk patients are encouraged to call OSEEGIB's health care management unit, 405-942-2180, to discuss benefits and options for their patients. They may obtain referred literature on the subject by calling their provider representative at 1-800-543-6044.

AMA organizing its '93 political education conference in D.C.

The 1993 AMA National Political Education Conference is scheduled for September 29-30, 1993, in Washington, D.C. Participants will learn how to make their grassroots efforts effective in the political arena. They also will have the opportunity to meet with other AMA members, members of Congress, administration representatives, and top political advisors.

The first day of the conference will be devoted to the legislative process—beginning with a legislative briefing to prepare participants to visit Capitol Hill for meetings with members of Congress. That evening they will host a reception for all members of Congress.

(continued)

In Memoriam

1992	
Francis Patrick Cawley, MD	April 17
Don Horatio O'Donoghue, MD	April 20
Billie Gene Henley, MD	April 24
Arlo Kenneth Cox, MD	April 27
Charles Victor Williams II, MD	May 1
Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28
1993	
Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Chester Randall Seba, MD	April 4
Edward Cotter Murray, MD	April 9
William Niebuhr Weaver, MD	April 20
Eric McLain White, MD	April 23
John Franklin DeJarnette, Jr., MD	May 1
Harold Alwin Smith, MD	May 4

Physician participation essential to success of FDA's MEDWatch

Physicians and other health care professionals are reminded that their participation in the MEDWatch program of the Food and Drug Administration (FDA) is critical to its success.

The program was instituted by the FDA to improve the safety of drugs, biologics, medical devices, dietary supplements, medical foods, infant formulas, and other regulated products by encouraging health professionals to report serious adverse events and product defects. MEDWatch is a comprehensive approach to the FDA's post-marketing surveillance and is aimed at more involvement by health professionals.

Clinical trials of a product typically include safety data on several hundred or several thousand patients. Once marketed, the product is used by a much larger population and additional data on its safety and efficacy may come to light. MEDWatch is intended to bring this information to the FDA's attention as soon as it is gathered by health professionals. The FDA hopes to make the such reporting of adverse events and product problems a routine procedure for health professionals in the field.

An important part of MEDWatch is a simplified reporting form that replaces five other forms previously issued for the same products. The self-addressed, one-page form, which can be folded and mailed postage free, will be made widely

(continued)

D.C. conference *(cont.)*

The second day focuses on specific techniques for increasing grassroots political/campaign skills, analysis of current issues, an overview of 1994 candidates and campaigns, and a review of the latest in health care reform. The AMA encourages physicians to attend and learn how the changing political environment of today will affect the practice of medicine tomorrow. Registration for AMA members is $395; hotel reservations must be made by August 30. For additional information and registration forms, contact OMPAC Director/Treasurer Robert Baker, 1-800-522-9452, 405-843-9571, or 918-743-9773.

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Louis Harris & Assoc. conducting survey on privacy in health care

Louis Harris and Associates, in collaboration with Dr. Alan F. Westin of Columbia University, currently are conducting a national survey of public attitudes on health-care information privacy and confidentiality issues. The issues have been raised by the increasing need for shared information using computer technologies, health identity cards, integrated data systems, and national health care reform.

Medical records contain information that individuals rightly consider highly sensitive. At the same time, medical information is needed to support medical care payment by insurance and government programs, for quality-of-care determination, for fraud reduction, development of professional-practice guidelines, and for creation of reliable data for cost-control efforts.

Dr. Westin, author of *Privacy and Freedom* (1967), noted, "None of the recent surveys on health care reform has dealt with the key privacy issues that will need to be addressed strongly and well if the public is to accept greater circulation and use of medical records. This survey will explore in depth what the public expects health care reformers to do by way of privacy protection."

The survey, begun in June, is examining topics such as (1) levels of trust Americans have in institutions that use their medical information; (2) experiences individuals have had with uses of such information; (3) attitudes about the use of one's medical information for various needs in health care administration and reform; (4) privacy-protection safeguards; (5) need for federal or state level medical-privacy legislation; (6) individual rights to access one's own medical records; (7) employer access to personal medical information; (8) attitudes toward privacy and how they correlate with attitudes toward health care reform; and others.

Survey respondents will include the American public, health care providers, insurers, professional association executives, and government policymakers. The survey field work will continue through July. Results and analysis will be released in early October at a national conference on privacy and health information to be held in Washington, D.C.

The survey is the fourth in a series of annual studies sponsored by Equifax that address the privacy concerns of the American public.

MEDWatch *(continued)*

available in several publications including the *Physicians' Desk Reference,* the *FDA Medical Bulletin,* and *AMA Drug Evaluations.* In addition, the agency has established a special toll-free telephone line and a computer reporting system.

Adverse events that should be reported include the patient's death, life-threatening illness or injury, hospitalization, disability, congenital anomaly, and experiences that require intervention to prevent permanent impairment of health. Information on regulated products, such a suspected contamination, questionable stability, defective components, and poor packaging or labeling should also be reported.

More than 50 organizations of health professionals have agreed to promote the program to their members. Among them are the American Medical Association, Pharmaceutical Manufacturers Association, American Dental Association, American Association of Blood Banks, American Nurses Association, American Osteopathic Association, American Veterinary Association, and Joint Commission on Accreditation of Health Care Organizations.

HEALTH DEPARTMENT

Polynuclear aromatic hydrocarbon toxicity

Percival Pott, an English surgeon, was the first to report a connection between occupation and cancer. In 1775, he described an unusually high incidence of scrotal cancer among London chimney sweeps and suggested it was due to their exposure to soot and ash. Since then, hundreds of polynuclear aromatic hydrocarbons (PAHs) are ubiquitous in the environment. PAHs are organic compounds consisting of three or more fused benzene rings containing only carbon and hydrogen. PAHs form when complex organic substances are exposed to high temperatures or pressures.

PAHs have been identified at several of the National Priorities List sites designated in Oklahoma for Superfund cleanup, in addition to many state-identified hazardous waste sites. Most PAHs in ambient air are the result of burning coal, wood, petroleum, petroleum products, or oil. Water and soil contain measurable amounts of PAHs primarily from airborne fallout. Water contamination also occurs from in-

(continued)

'Tis the season for venomous bites, stings

To the Editor: Venomous bites are now in season. High voltage low amperage direct current multiple shocks of short duration have been a safe, simple, and effective method of treatment and do NOT require specific vector identification. Using a stun gun of 50KV with 4.5 milliamps for an estimated one second per shock, multiple shocks are done through and around the bite to include all areas to which venom may have spread. Associated pain and systemic symptoms subside within a short time. Progression of tissue damage due to venom also ceases and does not recur.

Extending the series previously reported,[1] 528 spider bites, 54 stings, and 8 snake bites have now been treated in an unselected patient population—age range from 5 months to 93 years—with no complication from the shock procedure as outlined. All should be given broad spectrum antibiotics concurrent with tetanus prophylaxis.

The action of direct current on venom in tissues has not been elucidated in the laboratory, but venom degradation according to the theories of Kroegel and Meyer zum Buschenfelde[2] seems valid since the action of the venom is apparently stopped immediately and does not recur. The technique is simple, requires minimal equipment, and is safe and effective with no side effects except momentary discomfort.

ALTERNATING CURRENT IS ABSOLUTELY CONTRAINDICATED!

—Carl D. Osborn, MD
Ada

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MD praises Greenfield's work on antimicrobials

To the Editor: I wish to commend Dr. Ronald Greenfield for his outstanding articles on antimicrobial agents. I eagerly await each Journal to see his new work. In my thirty years of reading the Journal I have never seen a more practical subject as well covered. These types of articles are greatly appreciated by rural physicians who do not have libraries immediately available. I hope the Journal will continue with such articles reviewing current subjects.

—J.R. Priest, MD
Pawhuska

dustrial effluent and accidental spills. Charring meat or barbecuing food over a charcoal fire greatly increases concentrations of PAHs. Roasted peanuts and coffee, refined vegetable oil, and many other foods contain PAHs, and some crops such as wheat, rye, and lentils may synthesize PAHs. Cigarette smoke contains numerous PAHs. Filtered cigarettes remove some, but not all, PAHs from cigarette smoke inhaled by the smoker.

PAHs are absorbed through ingestion, inhalation, and dermal contact. They are metabolized in a number of organs and are excreted in the bile and urine. Because of their lipophilic nature, PAHs accumulate in breast milk and adipose tissue. PAHs generally have a low degree of acute toxicity to humans. Many are only slightly mutagenic or even nonmutagenic in vitro; however, their metabolites or derivatives can be potent mutagens. Interaction of PAH metabolites with DNA is believed to be the mechanism of PAH-related carcinogenesis.

The carcinogenesis of certain PAHs is well established in laboratory animals. Increased incidence of skin, lung, liver, and stomach cancer has been reported, as well as injection-site carcinomas. Animal studies indicate that certain PAHs also can affect the hematopoietic and immune systems, and can produce reproductive and developmental effects. Human effects associated with chronic exposure to PAHs include chronic bronchitis, dermatitis, cutaneous photosensitization, and pilosebaceous reactions.

Direct biological measurements of PAHs is neither cost effective nor clinically useful. The most common tests for determining exposure involve examining tissues, blood, and urine for the presence of PAH metabolites. In general, biological monitoring can be useful in determining whether exposure to PAHs has occurred, but is not clinically useful for evaluating individual patients because normal or toxic levels have not been determined. Individual variability, compounding effects of drugs or cigarettes, and nonspecificity of techniques are likely to complicate the interpretation of the results, especially in low-level environmental exposures.

Treatment of PAH-related disease begins with patient education. Persons exposed to potentially significant levels of PAHs should be aware of the increased risk of cancer and the additive effect of cigarette smoke and other toxic agents. Periodic evaluation of healthy patients who have been significantly exposed to PAHs, even in the absence of symptoms, is recommended to facilitate early diagnosis and intervention, should a malignancy develop.

Patient details his life-and-death struggle with health care regs

The following narrative was written earlier this year by an Oklahoma teacher during his recovery from a near-fatal asthma attack. In it he details for friends his struggle to survive amid the red tape and regulations of today's health care bureaucracy. Names have been changed to protect the patient's privacy.

"I knew that suddenly the worst asthma attack I have ever had just hit me.... I thought, *Even though I think I'm dying, I have to get my doctor's permission...*"

TUESDAY, APRIL 6, started like most days. I woke up with asthma, used my inhalers. They did not seem to open me up like they do most of the time, so I decided to just lie in bed and "practice calm breathing." I used the inhalers again. They began to work, so I knew this was going to be another good day. While at work that day, I had to use my inhaler two or three times to keep the asthma from coming back. This is not unusual. The kids have seen me use inhalers many times. In fact, there had been many days when I had asthma much worse than I had that day, so I did not worry too much about it. I did, however, write up my Substitute Lesson Plans Sheet for the next day, as I had done many times before when I could tell there might be a chance of having to be out of school the next day to go for a breathing treatment. Some of you even stopped by my room on your way out and asked why I was staying so late on our three-day snow week, and I told you.

Anyhow, here goes as best I can remember.

About 5:30, as I was getting ready to leave the school, I called Nancy and asked if she'd like me to stop off at Sonic for the two-for-one burgers. I did.

I arrived home about 6:00. We ate and watched the news. I could feel the heaviness of my breathing so I used the inhaler (Proventil) again. I have another that I am to use 5 minutes after the Proventil if it doesn't work (called Atrovent). I used this. On Tuesday nights Nancy has to take Holly to her dance class by 8:00. She asked me if I thought I'd be all right because this was about 7:15. My doctor had made the comment to me before that I might want to start thinking about getting a breathing machine; then I would be giving myself the same medication that the emergency rooms would be giving me and even though breathing machines are expensive—emergency rooms at hospitals are even more expensive. He also had stated that the medication they gave me in the breathing treatments was exactly what I already had in my inhalers—"so don't be

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Style in Medical Writing

This editorial was submitted by JOURNAL editor Ollie W. Dehart, MD. It was written by Sir Andrew Macphail, first editor of the Canadian Medical Association Journal, *and appeared in the January 1911 issue (Vol. 1, No. 1, pp 70-73). It was reprinted in that journal's June 15, 1992, issue.*

IT HAS NOT ESCAPED NOTICE that all important scientific observations have been records with a singular fitness of words. The best scientists have been the best writers upon science. Huxley, Tyndale, and Osler are good writers of English, because the style of each is inseparable from the man. His way of writing is part of himself, since a pen is not a machine which proceeds automatically, once it is set in motion. It must be governed by a hand which, in turn, is directed by a mind.

There are three kinds of writers: those who never think at all; those who think only as they write; and those who have thought before they take the pen in hand. Careful observers belong in the last category, and that is the reason why they write so well. Poor writers employ phrases. Good writers employ words; and they compel each word to give a proper account of itself. They put it to the question. They scrutinize it with the same care as they exercise towards the fact which they propose to describe. If it is weak, or worn, or superfluous, they cast it aside, as a good craftsman rejects imperfect material. Their writing, then, has symmetry and strength, and fitness for the work which it is intended to perform.

On the other hand, loose and slatternly writing is a mark of a slovenly habit of mind. Sheer laziness will produce the same result, since easy reading is hard writing. The trade of the pen must be learned, and he who is not willing to practise it, at first for the fire, has no right to take into his hand that ob-

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Asthma attack *(continued)*

afraid to use the inhalers more when you need to."

I asked Nancy if she thought she had enough time to go to my mother's nursing home and borrow her breathing machine. She did. She arrived back home at approximately 7:30. She brought enough medication for two breathing treatments. She waited about 5 minutes more until I finished the treatment. I said, "I think I'm going to be okay, so go ahead and take Holly to her dance class."

About 5 minutes after Nancy left, I knew I had made a bad mistake. I thought I had the asthma under control, but that last attack became very severe so suddenly I was about to pass out. I knew I had to go to the emergency room. I had already done all I could do with every medication I had, and nothing was working. The clinic was closed, I was hardly breathing, and the asthma was getting worse by the second.

Then I tried to start thinking about all the rules I had to follow in exact order before I could get permission to get help at an emergency room under my HMO—*the most costly HMO offered by our school—I thought I had the best.*

You may think, "Why would he stop and think of HMO rules at a time when he needed to be in the emergency room?"

Well, because my HMO and the doctor made this very clear to me after the asthma attack that required me to go to the emergency room for breathing treatments and medication on the night of our school carnival.

I paid my $50.00 co-payment, then found out that my HMO would not pay their part because they do not consider an asthma attack an emergency. Unless you first talk to your doctor and let him decide.

This is what you're supposed to do when you are dying with asthma:

You are expected to call your primary care doctor first.

Wait for him to call you back.

Then you have to say something like this: "Oh, Doc. I cannot breathe, and my heart is stopping—and oh, yeah, I'm passing out—Do you think these symptoms are important? Because you see, even though I went to college as long as you did, and I've lived with asthma 53 years, I am not able to make such a hard decision."

THEN ANSWER questions like these:

Have you tried your inhalers? They don't seem to be working? Don't you think if you just calm down you'll be okay? Why didn't you come into the office today when it was open?

I didn't have time for this. I couldn't think. Yet I knew I had to, that there were certain rules I had to follow. What were they?

I knew that suddenly the worst asthma attack I have ever had just hit me. And it was so sudden, because I thought I had just had it

Medical writing *(continued)*

stinate and refractory tool. It is easy to pour out a flux of words. It is difficult to range them in order, and make them obedient to the purpose for which they were created. When a man spreads over ten pages what is really exhausted by five, his offence is due to lack of perception, to incapacity or unwillingness to take pains, to indifference to the time and feelings of others, —in short, to sheer selfishness or downright laziness.

But, fortunately, most men, with the exception of editors, are not compelled to read. They can protect themselves by throwing down the book and refusing to open the paper. Practitioners of medicine are too intelligent by nature and too critical by experience to mistake prolixity for learning, and the employment of loose phrases for knowledge. An orator may be diffuse: a writer, in a publication which makes a pretension to being scientific, must not. Presumably, most men desire to have their writings read. Then, they must pay the price.

There is probably more bad writing in medical journals than in any other kind of periodicals. For this there is a variety of reasons. Medical men are without leisure, and there is so much in medicine about which something may be written, that they lose their way. Besides, it is a common delusion that the mere fact of attendance for four or five years upon lectures in a faculty of a university confers upon a man those qualities of aptitude, precision, and harmony, which are commonly called style. On the contrary, the pursuit of a single, dominating interest, as Mr. Asquith told the students of Aberdeen University, limits a man's breadth of outlook and the range of his intellectual curiosity; it dulls his zest and diminishes his eagerness to know and integrate into himself the best that has been thought and written for the enrichment of his mind. In short, it is a bar to the perception of what is good and what is evil in the art of writing.

under control before my wife left.

Then I thought, *Even though I think I'm dying, I have to get my doctor's permission...*

I looked frantically for the doctor's number. Called his answering service. Then I realized I was passing out fast. I searched for a shot I was supposed to give myself if the attack was severe enough, called epinephrine. I found it. I could not get it to work. I couldn't keep my thoughts together enough. Something told me, "You don't have enough time to give yourself a shot, much less wait for the doctor to call back, and *you don't have time to call 911—you'll be dead before they get here."* I remembered it had just happened to a popular girl at one of the local high schools last year. She died in her mother's lap while waiting for the ambulance.

I decided if I was going to make it, I'd have to drive myself, because by this time I could only gasp, "Oh, God, help me! Oh, God, help me!"

I remember making it to my car. I remember thinking that my HMO required me to go to either Riverton or Parkside Hospital. I thought, *I'll drive down First Street to Maple and go to Parkside, and since I only live three blocks from City General, and have to pass right by it, if I don't think I can make it to Parkside I'll just stop at City General and pay them out at ten dollars a month. That's better than dead.*

I hardly remember leaving my house. I don't remember passing City General. I only remember the pain in my chest and gasping, "Oh, God, help me!" "Oh, God, help me!"

All of a sudden I realized where I was. I was about a mile past City General and still about 3 or 4 miles from Parkside. I knew my only chance was to get back to City General.

I don't remember turning the car around. I don't remember driving back to the hospital (I didn't even remember passing it in the first place). But somehow my car ended up in the emergency parking lot, and they said I walked into the hospital emergency room. I guess God sent an angel to drive for me because I sure don't remember driving.

My doctor told me that he came into the emergency room about thirty-five minutes after he had received the call.

Nancy found me about 9:30.

The next thing I remember was I was tied to the bed, couldn't move, and had tubes everywhere. This was about 3:00 A.M. Then I saw the most wonderful angel faces looking at me. They were the faces of my wife and son. I knew that, if I was dead, I had made it to the right place, because they were there, and I was too.

While in intensive care I heard, "You're a lucky person, Mr. Anderson. Everyone thought you were not going to make it."

Days later, after the tubes were out and I could talk, I said to my doctor, "Thanks for saving my life." He said, "Don't thank me, I just

Much of the technical business of medicine is handiwork. A man may be a most expert operator in surgery, and yet be no more qualified to set forth his methods in plain terms which all may understand than a craftsman can explain by written symbols how he tinkers a kitchen clock. But a man who is intelligent enough to be a surgeon is also intelligent enough learn how to write down what he wants to say in simple, accurate terms.

ACCORDINGLY, IN MEDICAL JOURNALISM, the great standards of English speech have been lost sight of, and there is a consistent effort to translate plain terms into a kind of jargon. It is, no doubt, a convenience in the laboratory or in the outpatients' department that a jargon should be employed; to refer to the tubercle bacillus as the "t.b.c."; to describe a diseased joint as "a Charcot"; inability to retain the eyeballs in conversation as "Moebius present"; and the absence of a certain reflex as "a Babinski." The employment of these terms in writing is a mark of a slovenly and slow-working mind.

What is worse, many writers appear to think that a good style may be achieved by the use of flamboyant language. The following will serve as an illustration: "Life is a biologic function. Living matter has a definite chemic composition, wasting by oxidation and reintegrating by the assimilation of new matter. The specific feature of living matter is its chemic mutability, and which, mutatis mutandis is a history of food changes plus the mechanisms by which its potential energy is converted into vital force." Or, again, "the disequilibration associated with the cessation of ovulation and menstruation is a menace to mental integrity." Also, there are many phrases which, although quite proper in themselves, have become worn and threadbare by constant use, and their continual employment destroys all sense of freshness. Such expressions as "aetiological factor," "pathological findings," "diagnostic significance," "clinical picture," and "symptom-complex"

(continued)

Asthma attack *(continued)*

picked up the pieces. The person you need to thank is Dr. Carter and the emergency room crew. They did a marvelous job."

I also heard someone say that they had worked on cadavers in med school with more oxygen in their blood than I'd had in mine

You don't know how hard it is for me to talk about this, because talking about it makes me experience the pain and breathlessness of the attack. Yet I feel like I must, because I'm so thankful I'm still alive.

Still, I'm very angry that an insurance company can make such rules for asthmatics, or anyone who has a disease that can kill so fast.

I DON'T KNOW WHY I've been given another chance at life, but I do know I'm going to try to get severe asthma attacks considered an emergency and that asthmatics may go for emergency, covered help at any time they have used all prescribed medications and the asthma is getting worse, because asthma is too unpredictable, too fast acting, too deadly to have to wait for permission, (the proof is that too many die from it each year it), and that the danger of dying from an asthma attack is almost as great as dying from anything else they consider an emergency. Some people are in nursing homes unconscious because they waited too long to get to the emergency room.

This is not an illness that will sometimes allow a person to know when they to have time to call and ask for help. Sometimes they do, and everything is good. Sometimes they don't, and they end up deader than Elvis.

I have a very good doctor. He has to follow the same silly rules too.

My HMO handbook considers asthma attacks as URGENT CARE. It states, "If you need urgent care, call your HMO Primary Care Physician and explain the illness or injury. The Physician may instruct you in a method of home care, ask that you come to the office, or advise you to go to the emergency room."

This has to be changed for asthmatics. There are many times *I would have been dead if I had followed these silly rules.*

If I sound like I'm upset over this—I AM.

Because of these silly rules I hesitated too long to go for medical help.

I had emergency and intensive care workers tell me I had died and was brought back to life, and that it was a miracle I was still here.

My wife and daughter were told I was lucky to still be alive.

All the above is really awful, but that's not the worse part of the experience. The worse part of all is they cut my clothes off me, and I had on a dirty pair of shorts. I guess moms are always right about those things.

—Barry

Medical writing *(continued)*

were once good; but they have long since fallen from their high estate.

A careful comparison of the older issues of medical journals with the newer ones forces one to the melancholy conclusion that, in respect of style, the old were better than the new. The fault is largely with the younger writers. There are a few amongst them who have that capacity for good writing which is commonly found in the contributors of many years ago, and is still found on the editorial pages of the Journal edited by Dr. John Ferguson, himself a veteran.

Deaths

Dan Earl Woodson, MD
1927 - 1993

Dan E. Woodson, MD, OSMA Life Member, died June 4, 1993, in Oklahoma City. A native of Poteau, Dr. Woodson earned his medical degree at the University of Tennessee College of Medicine, Memphis, in 1957 and began a general practice in Boonville, Ind., the following year. He began postgraduate training in anesthesiology in 1960, finishing in 1962 and establising a practice in Oklahoma City shortly thereafter. Dr. Woodson served on active duty with the U.S. Army's 45th Division from 1950 to 1952.

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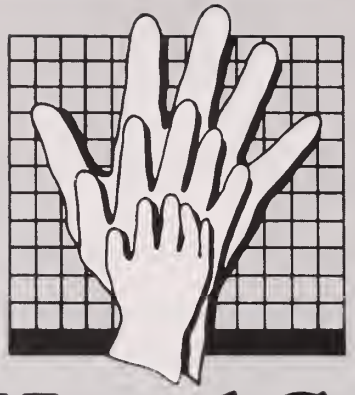
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THE LAST WORD

■ **The Unprofessional Conduct Section of** Oklahoma's physician licensure law has been amended to include "Nonconsensual physical conduct which is sexual in nature...."

■ **The OSMA Board of Trustees has authorized a** $25,000 expenditure from OSMA's Loan and Scholarship Fund to help fund a program for medical students working with doctors during the summer. The training program, sponsored by the Oklahoma Chapter of AAFP, has more than fifty medical students and 50 physicians signed up for this year's program. Dr. Michael L. Winzenread, Oklahoma City, is program coordinator.

■ **The latest in cellular phone services and** equipment is now available to OSMA members at a special rate from Southwestern Bell Mobile Systems in Oklahoma City. For more information contact OSMA Associate Director Lyle Kelsey or call Pamela Estep at Southwestern Bell Mobile Systems, 405-752-6332 or 405-640-8444.

■ **Twelve students were graduated May 14 from** the Interdisciplinary Training Program in Child Abuse and Neglect, sponsored by the Center on Child Abuse and Neglect, Department of Pediatrics, University of Oklahoma Health Sciences Center. The nine-month, graduate level program provides experiences for students within specific disciplines, as well as cross-discipline training designed to increase their awareness of the roles of other professionals dealing with child abuse and neglect. This year's graduates represented the fields of law (5), medicine (2), psychology (4), and social work (1).

■ **Carlos A. Garcia-Moral, MD, Oklahoma City** orthopedic surgeon, has received an award from the American Society for Surgery of the Hand for his study on the significance of the hand in American Indian history. It is the first time a physician from Oklahoma has received the Best of Show award for an exhibit at one of the society's meetings.

■ **The Oklahoma State Board of Medical Licen**sure and Supervision reminds physicians that *it is illegal to allow an unlicensed person to practice.* The board licenses medical doctors, physician's assistants, physical therapists and assistants, occupational therapists and assistants, dietitians and provisional licensed dietitians, athletic trainers and apprentices, and electrologists. Anyone practicing any of these professions must be licensed *prior to beginning practice.* Persons supervising an unlicensed individual without formal written authority from the board *may be subject to disciplinary action* including reprimand, probation, or revocation of licensure. Always ask to see the official letter/certificate of any person you are asked to supervise or verify it directly with the board office (405-848-6841).

■ **The American Board of Medical Specialties** announces the release of *The Official American Board of Medical Specialties (ABMS) Directory of Board Certified Medical Specialists.* The publication, produced in cooperation with Reed Reference Publishing (*Marquis Who's Who)*, has been a prime objective of the ABMS Assembly for the past decade.

■ **The American Board of Medical Specialties** has renamed its Yellow Pages Program. In January, the name was changed to the ABMS Public Education Program to more accurately reflect its true purpose. The program was begun in 1989 to permit physicians certified by a member board of the ABMS to publicize their credentials under the ABMS trademark and specialty board headings in the Yellow Pages. The listings are also serviced by a toll-free number, 1-800-776-CERT, for consumers to verify the certification status of physicians not participating in the program. Some 1,000 calls are received each day, and more than one million callers have used the number to obtain information about a physician's certification or about locating a board certified specialist. The toll-free service includes referring the caller to the ABMS listings in the Yellow Pages.

■ **The widow of a University of Oklahoma Col**lege of Medicine alumnus has named the OU Foundation beneficiary of a trust, the proceeds of which will exceed more than $112,500 for medical student scholarships. The bequest of longtime Norman resident Mary Jo Thomson Ragan, who died in 1991 at the age of 80, will fund an endowment to provide grants for students at the OU College of Medicine in Oklahoma City in memory of Mrs. Ragan's husband, the late Dr. T.A. Ragan. Dr. Ragan, who died in 1982, practiced in Norman from the 1940s until his retirement in the late 1970s. He was a 1932 graduate of the OU School of Medicine.

Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosponne. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The usa of fibrates alone may occasionally be associated with myopathy. The combined usa of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, if is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 6 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with aspirin, *antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid, or probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL is administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theorefically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adversa Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4 0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1 9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1 2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions**.)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

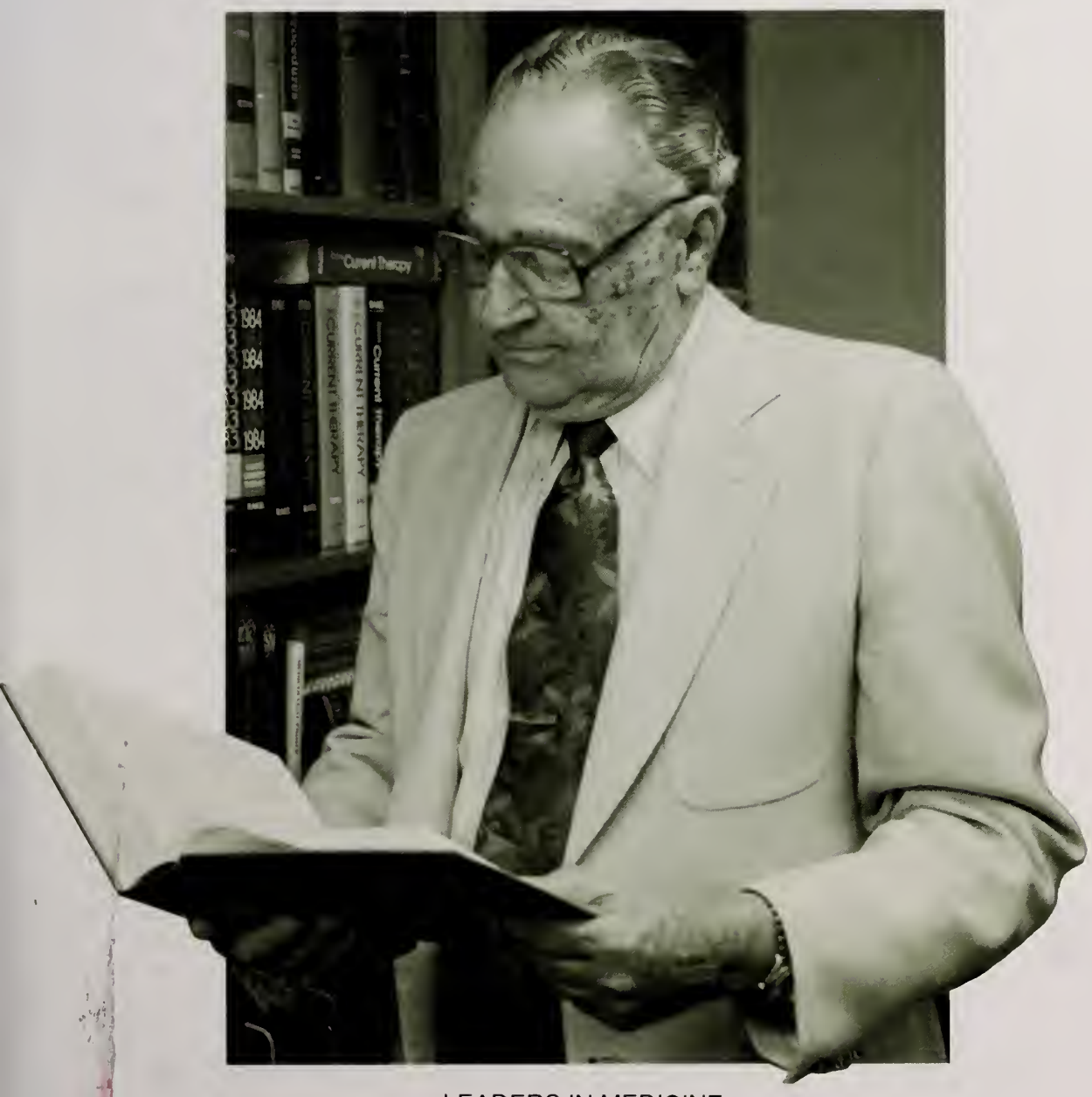
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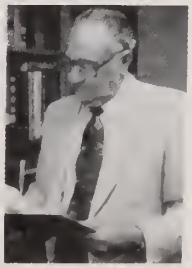
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Also, since *all* State Board rules and regulations were written by lawyers for use in a legal adversary system, we suggest that prime purpose will best be achieved by emphasizing an interpretive role. It is a fact of life that, in any dialogue with attorneys or police, the principles and values of the physician require translation and interpretation. For example, we note that every practitioner originally licensed by the Board of Medical Licensure would now be considered "incompetent" to practice, due to knowledge obsolescence. And everyone presently licensed will become incompetent sometime in the future. Because the cognizance of physician incompetence requires physician expertise, a Board of wise and objective physicians must *then* interpret "competence" to those State functionaries who will be empowered to execute the law.

Treatment fashions, fads, and fancies come and go. Social diseases and disabilities wax and wane, and substance abuse chemicals are ubiquitous. These variations of human behavior affect physicians as well as patients. The Board of Licensure, as a panel of physicians, has the awesome duty to bring current medical knowledge of all these foibles to the medical licensing function so that the public is protected and the physician always meets objective standards.

Our present society loves psychotropic drugs, and a black market results. Illegal drug-seeking behavior is frequent, and some unscrupulous practitioners profit from this drug lust by selling unnecessary prescriptions. Police surveillance counts of the number of controlled drug prescriptions issued by individual physicians helps in discovering these unprincipled practitioners. However, this detection device places a heavy burden on the Board of Licensure in their interpretive role on the "good" versus the "bad" physician. Prescription counts are useful as a screening device in the police search for the careless physician, but they can only be a red flag that triggers the Board's evaluation of the competence, ethics, or malfeasance potential of the practitioner. The count itself probably should never be the principle evidence in a formal allegation of malfeasance or incompetence; corroboratory evidence is necessary.

The nature and circumstances of the individual practice should be appraised by the physicians on the Board prior to a legal allegation of malfeasance. We remember that the wise methadone clinic doctor may prevent burglaries with pills. Long-term prescriptions for benzodiazepines probably reduce drunk driving fatalities. Human depression is widespread, disabling, recurrent, and sometimes helped by controlled drugs as ancillary treatment.

The greedy physician who "sells prescriptions" should be eliminated from our society, but the Board of Licensure has a delicate and crucial task in interpreting physician practice patterns so that the caring clinician with many emotionally disturbed patients is not incorrectly accused of carelessness or criminality. "The good of the many" includes the continued licensing of physicians who shall not be afraid of correctly prescribing controlled medications.

Ray V. McIntyre, M.D.



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PRESIDENT'S PAGE

G. Lance Miller, MD

Our Window of Opportunity



Last month our Board of Trustees made a momentous decision.

In late June, the Special Committee on Managed Care delivered its long awaited recommendation. This committee worked diligently and I commend the members for their efforts. The recommendation is for this association to consider the formation of a statewide insurance network.

It is my personal opinion that there is every reason for this state's physicians to develop their own insurance company, and very little reason not to do so.

Until now, physicians' services have been exploited by fiscal intermediaries for their own financial gain. By forming our own organization, owned, managed, and controlled by physicians, profits previously realized by businessmen and stockholders can be used to improve quality of care and to allow physicians to regain some degree of control and maintain a competitive edge.

In all of this I emphasize *control*. For too long we have passively abdicated control of health care to business entities who view medicine as just that—a business which must turn a profit no matter the consequences.

If you are having difficulties imagining a managed competition form of health care, one without physician-owned competitive elements, I refer you to an article by Sidney Marchasin in the June 2 issue of *The Wall Street Journal*. Mr. Marchasin describes the gruesome situation in the Los Angeles area where the private practice of medicine is already practically extinct.

It is predicted that soon the majority of health care for the 13 million people in that area will be delivered by ten or fewer giant medical networks which have been dubbed "supermeds." The author envisions the future of health care under such a corporate (bottom line) system, and frankly the conclusions are abhorrent to me personally.

Two paragraphs from this article are particularly cogent and I feel it is important to share them with you:

> Many groups and agencies are now watching over the cost of health care. But what we desperately need is someone to watch over the welfare of the sick patient. The family doctor has always served that role. But physicians entering into giant networks lose their autonomy and their power. One of their primary obligations is to satisfy corporate headquarters.
>
> ...Cost, access and quality are all intertwined, and we cannot address one of these concerns without addressing them all.

Your Board of Trustees does not want this to happen in Oklahoma. Therefore, the Board voted by mail to have the OSMA develop a statewide physician provider network. Your leadership has begun the planning phase of this important project. Several state associations have already implemented their own networks including Connecticut, South Dakota, and South Carolina. Other associations are forging ahead with similar programs. It is also important to know that several associations have attempted statewide insurance programs and failed.

It is our goal to study all those programs and learn what has been successful and what has not worked—thus assuring, as best we can, that our program will succeed.

There are many complex issues to deal with in organizing an insurance company, but if other state associations can deal with them, so can we. Antitrust issues are foremost, but discussions with other states' association officers convince me those issues are not a major roadblock.

Key elements in this effort are financial risk to the individual physician and a very tightly controlled utilization review process. Considering that this project offers all of us the opportunity to regain some element of control of our practices, I cannot imagine that the risk element weighs particularly heavy on our minds.

We have a small window of opportunity at this point in history. Physicians in other states are, at this moment, seizing the opportunity, taking the risks necessary, and moving forward with plans to be active players in the game of health care control.

Do we, the physicians of Oklahoma, have the vision and the intestinal fortitude to follow the same path? We shall see.

G. Lance Miller, MD





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Symposium on Antimicrobial Therapy
XI. Antituberculosis Agents

Ronald A. Greenfield, MD; Harold G. Muchmore, MD

This is the latest paper in Dr. Greenfield's symposium, begun in October 1992.

WITH THE FIRST TEN SEGMENTS OF THIS SYMPOSIUM, we have completed discussion of what is usually considered to be antibacterial chemotherapy. With this segment we will continue with particular discussion of a single bacterial infection, tuberculosis. Does tuberculosis warrant such individual attention? Most assuredly it does. Worldwide, 1.7 billion individuals harbor latent tuberculous infections, 8 to 10 million new cases of active disease occur annually, and 3 million humans die of tuberculosis each year.[1]

Koch identified the tubercle bacillus in 1882. By 1910, when such data began to be collected in earnest, the incidences of new tuberculin responders, new active cases of tuberculosis, and mortality due to tuberculosis in the United States were in decline, likely due to general improvement in sanitation conditions. The rate of this decline rapidly accelerated, beginning in the 1940s, with the introduction of modern antituberculosis chemotherapy. However, an unprecedented resurgence of tuberculosis in the U.S.A. began in 1985 and continues through the present time.[2] From 1985 to 1991 there was an 18.4% *increase* in new cases of tuberculosis reported in the U.S.A.[2] If that is not frightening enough, some of this increase is due to outbreaks of so-called multidrug-resistant tuberculosis, i.e., infection with tubercle bacilli resistant to the action of multiple antituberculosis agents.[2] We may be staring into the barrel of a loaded gun signalling the beginning of a national and global pandemic of multidrug-resistant tuberculosis. Even if this does not ensue, the global mortality due to coinfection with human immunodeficiency virus (HIV) and the tubercle bacillus in the next several decades will be astronomical. All of us need to be educated to action now.

There are multiple reasons for the resurgence of tuberculosis. Perhaps chief among these is the pandemic of HIV infection. Patients with HIV infection commonly develop tuberculosis, are susceptible to acquisition of new tuberculosis, develop noncharacteristic clinical manifestations of tuberculosis, and can exhibit an accelerated clinical course.[3] General social conditions, including the problems of parenteral drug abuse and homelessness, are also related to the current resurgence of tuberculosis. Physicians are not innocent bystanders either: complacency about diagnosis and treatment of tuberculosis are important factors in the resurgence of tuberculosis. An additional factor is the decreased and currently inadequate financial support for public health programs directed at tuberculosis control.

To avert a pandemic of multidrug-resistant tuberculosis, immediate action is required. Some of the steps for which physicians are responsible are as follows. Efforts must be directed to early diagnosis of tuberculosis. Screening for tuberculosis must be reemphasized and implemented, not only in those with HIV infection,

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but in all individuals. Patients with known or suspected tuberculosis must be appropriately isolated; specifically, such patients should be isolated from the time of admission to hospitals. Effective antituberculosis therapy must be promptly instituted in patients with active disease. Over the past few decades, tuberculosis became a disease treatable appropriately by most physicians. I am afraid that appropriate treatment of many cases of tuberculosis today again requires expert consultation. Decisive steps must be taken to ensure that patients with drug-susceptible tuberculosis adhere to their therapeutic regimen. Partially treated individuals are the source of multidrug-resistant tuberculosis, and epidemiologically speaking, are likely of greater potential harm to the community than untreated individuals.[1] In this regard, everyone with active tuberculosis should, at least initially, receive therapy under direct observation, so-called directly observed therapy or DOT.[4] Patients with tuberculosis must be reported to local health departments, and contact tracing and appropriate prophylactic therapy must be aggressively instituted.

Many complex medical and social issues have always been involved in the treatment of tuberculosis, and these are much beyond the scope of this symposium. With that introduction off our chest, we are going to return to a drug-based approach.

We will conclude with some basic principles of tuberculosis treatment. As noted above, consultation is increasingly required for determination of appropriate therapy for tuberculosis, but care of patients with tuberculosis will increasingly become an important issue for most physicians.

The Bases for Chemotherapy

Before beginning discussion of individual antituberculosis agents (Table 1), the bacteriological basis for treatment of tuberculosis will be reviewed.[5] *Mycobacterium tuberculosis* is a slow growing organism, with a doubling time of about 20 hours under favorable conditions. In unfavorable conditions, it will grow only intermittently or remain dormant for a long period. There is a high rate of mutation to resistance to antituberculosis drugs: a newly isolated "wild" strain of *M. tuberculosis* will have one of every 10^5 to 10^8 bacilli resistant to any single antituberculosis drug. These relatively rare resistant organisms can quickly replace all the original susceptible bacilli in a patient receiving inappropriate therapy. These basic biological features of *M. tuberculosis* account for the need for protracted therapy with multiple drugs.

To explain the response of tuberculosis to drugs, Mitchison developed a theoretical model of tuberculosis infection.[6] He proposed that there are several major subpopulations of *M. tuberculosis* in human infection, and that each of these has a distinctive metabolic status and thus a distinctive responsiveness to chemotherapeutic agents. In the wall of cavitary lesions, *M. tuberculosis* is in rapid growth phase, due to the favorable neutral pH and high oxygen tension. This subpopulation is particularly susceptible to isoniazid, and susceptible to a lesser degree to rifampin, streptomycin, and ethambutol. A second subpopulation exists intracellularly and in areas where there is an active inflammatory response. This subpopulation is particularly susceptible to pyrazinamide, whereas isoniazid, rifampin, and ethambutol are less active. The third subpopulation is located in caseous material where the pH is neutral but the oxygen tension is low; these organisms have occasional growth spurts. This subpopulation is best killed by rifampin because its bactericidal action starts very quickly. A fourth subpopulation is dormant and generally resistant to all drugs. Constant shifting between these various subpopulations is proposed in this model.

Table 1. Antituberculosis Agents

First-Line Antituberculosis Agents
Isoniazid
Rifampin
Ethambutol
Pyrazinamide
Streptomycin
Second-Line Antituberculosis Agents
Para-aminosalicylic acid
Cycloserine
Ethionamide
Capreomycin
Viomycin
Other Agents Used As Antituberculosis Agents
Other aminoglycosides
Fluroroquinolones
Clarithromycin
β-lactam/β-lactamase inhibitor antibiotics
Clofazamine

The concepts of bacteriostatic and bactericidal have been very difficult to apply to antituberculosis agents. A more useful categorization has been proposed by Mitchison.[6] There are three groups in this classification: (1) drugs with resistance prevention activity, (2) drugs with early bactericidal activity, and (3) drugs with sterilizing activity. Drugs with resistance prevention activity, when combined with others, prevent emergence of resistance to the companion drug. Isoniazid and rifampin are the most effective agents in this category, followed by ethambutol and streptomycin. Drugs with early sterilizing activity induce a rapid decrease in viable bacilli. The most effective agent in this category is isoniazid, followed by rifampin and

ethambutol. The drugs with sterilizing activity reduce the relapse rate to a minimum within a short period. Most effective in this regard are rifampin and pyrazinamide; isoniazid is weaker; streptomycin and ethambutol have little activity.

In view of these fundamental properties of the microorganism and the drugs used for treatment of the infections it causes, all patients with active tuberculosis require combination chemotherapy. A direct corollary of this principle is that *one* drug should never be added to a failing or failed regimen; this is the moral equivalent of single drug therapy because it must be assumed that the microorganism has developed resistance to all components of a failing or failed regimen. With this background, we can now discuss the individual agents used for treatment of tuberculosis.

Isoniazid

Isoniazid (Hyzyd®, Niadox®, Niconyl®, Nydrazid®), or more formally *iso*nicotinic acid *h*ydrazide (therefore INH), a synthetic antimicrobial, was introduced in 1952 and remains the mainstay of antituberculosis chemotherapy. Its primary mechanism of action is inhibition of synthesis of mycolic acid, a principle component of mycobacterial cell walls.[7] Primary resistance to isoniazid is unusual in Oklahomans, but varies considerably worldwide.[1] Approximately 1 in 10^6 bacilli of a sensitive strain of *M. tuberculosis* are primarily resistant, and these will emerge if isoniazid is used alone to treat active tuberculosis. These strains demonstrate decreased uptake of isoniazid.[7] Isoniazid is remarkably devoid of significant antimicrobial activity other than against mycobacteria.

Isoniazid is well absorbed after oral or intramuscular injection and is widely distributed throughout the body. Usual dosages of antituberculosis drugs are summarized in Table 2. In the presence of inflamed meninges, cerebrospinal fluid concentrations of isoniazid may equal serum concentrations.[7] Isoniazid is excreted primarily by hepatic acetylation by N-acetyl transferase and subsequent renal elimination of the metabolite. Sufficient quantity of drug is excreted in the urine in microbiologically active form for therapeutic efficacy. The serum half-life is determined by genetic inheritance of rapid or slow acetylation status. The clinical significance of acetylation status is not clearly determined. Dosage modification of isoniazid (50% reduction) is required only in the presence of severe hepatic insufficiency.

A number of drug-drug interactions involving isoniazid are noteworthy.[8] Daily alcohol consumption may increase the rate of acetylation of isoniazid and thus decrease efficacy and increase the possibility of hepatitis. Aluminum-containing antacids may decrease isoniazid absorption. Isoniazid may increase serum levels of concomitantly administered phenytoin (Dilantin®). Concurrent administration of isoniazid and disulfiram (Antabuse®) may cause psychotic episodes due to altered dopamine metabolism. Patients taking isoniazid may be more susceptible to acetaminophen hepatotoxicity.

As is widely known, the most common significant adverse effect associated with isoniazid therapy is hepatitis. Pathogenesis probably involves a direct hepatotoxic effect of the acetylhydrazine metabolite.[9] The incidence of hepatitis increases with age: it is rare in patients under 20 years of age, occurs in ≤0.3% of patients age 20 to 34 years, occurs in ≤1.2% of patients age 35 to 49 years, occurs in ≤2.3% of patients of age 50 to 64 years, and may occur in as many as 8% of patients age ≥65 years.[10] All patients taking isoniazid should be advised of this possible adverse effect and to discontinue medication and contact their physician if symptoms of hepatitis develop (such as loss of appetite, malaise, anorexia, nausea, vomiting, jaundice, dark urine, elevated temperature, and right upper quadrant abdominal pain). Regular communication (at

Table 2. Usual Dosages of Antituberculosis Agents for Aduts

Agent	Daily Dosage	Intermittent Dosage (2-3/week)
Isoniazid	5-10 mg/kg up to 300 mg	15 mg/kg up to 900 mg
Rifampin	10 mg/kg up to 600 mg	600 mg
Ethambutol	15-25 mg/kg	50 mg/kg
Pyrazinamide	15-25 mg/kg	50-60 mg/kg
Streptomycin	15 mg/kg up to 1 gm	15 mg/kg
Para-aminosalicylic acid	250 mg/kg to 12 gm	Not indicated
Cycloserine	10 mg/kg up to 1 gm	Not indicated
Ethionamide	10-15 mg/kg up to 1 gm	Not indicated
Capreomycin	15 mg/kg up to 1 gm	1 gm
Viomycin	Not indicated	2 gm twice weekly
Ciprofloxacin	1000-1500 mg	Not indicated
Ofloxacin	600 mg	Not indicated
Clarithromycin	1000-2000 mg	Not indicated
Clofazamine	100 mg	Not indicated

Adapted from Reference 5

least monthly) between the patient and health care workers regarding hepatitis is advised; however, the utility of scheduled laboratory measurement of hepatic enzymes is controversial. Mild increases in serum transaminases will occur in up to 10% of patients receiving isoniazid; most physicians will continue therapy unless the transaminases are greater than 3 to 5 times the upper limit of normal; some physicians will discontinue therapy in asymptomatic patients for this indication.[8] Isoniazid-associated hepatitis can be fatal, but definitive data about which patients may develop fatal hepatitis are not available. Postpartum patients may be at particular risk for fatal hepatitis.[11]

Isoniazid also causes increased urinary excretion of pyridoxine (vitamin B_6) and may produce symptoms of pellagra (vitamin B_6 deficiency) such as peripheral neuritis, rash, and anemia. This adverse reaction is dose dependent. One might anticipate pellagra to be more common in those with marginal nutritional status. These side effects are completely preventable by pyridoxine supplementation. Most physicians routinely prescribe pyridoxine 10 to 50 mg PO daily for all patients taking isoniazid. Pyridoxine supplementation also reduces the likelihood of some central nervous system toxicity that is not clearly related to pyridoxine deficiency.[8] Isoniazid overdosage should be treated with pyridoxine acutely.[5]

Less common adverse effects of isoniazid therapy include seizures (due to decreased brain gamma aminobutyric acid that is derived from pyridoxal phosphate), optic neuritis, psychotic reactions, arthralgias, vasculitis, shoulder-hand syndrome, and agranulocytosis. Hypersensitivity reactions including fever, rash, and urticaria are also uncommonly encountered.[8] Adverse reactions associated with antituberculosis therapy are summarized in Table 3.

Rifampin

Rifampin (Rifadin®, Rimactane®; called rifampicin in the United Kingdom) is a semisynthetic derivative of a complex macrocyclic antibiotic, rifamycin B, produced by *Streptomyces mediterranei.* As with streptomycin and isoniazid, the release of rifampin revolutionized treatment of tuberculosis.

The mechanism of rifampin action is inhibition of bacterial DNA-dependent RNA polymerase at the β-subunit.[12] This results in a suppression of the initial chain formation in RNA synthesis. The combination of isoniazid and rifampin effects clearance of tuberculosis in animal models superior to that achievable with any other combination. Rifampin is active intracellularly and against slowly replicating bacilli, perhaps explaining its synergistic activity with isoniazid. One-step resistance emerges if rifampin is used alone, precluding this possibility. The mechanism of resistance is alteration of the β-subunit of DNA-dependent RNA polymerase. Rifampin has considerable antimicrobial activity other than that directed against mycobacteria.[12-14]

Rifampin is well absorbed when taken orally. Rifampin can be administered intravenously in patients unable to take oral medications. Rifampin is extensively distributed throughout the body; therapeutically effective concentrations are achieved in cerebrospinal fluid in the presence of inflamed meninges. Approximately one-third of rifampin is excreted unchanged in bile, one-third is excreted in bile as an equally active metabolite, and one-third is excreted in urine.[8]

Rifampin has many important drug-drug interactions; it is a potent inducer of hepatic microsomal enzymes. Rifampin decreases serum concentrations and/or therapeutic effects of warfarin anticoagulants, cardiac glycosides (digitalis), oral hypoglycemics, oral contraceptives (may result in pregnancy), corticosteroids, narcotic analgesics (may result in withdrawal syndrome), cyclosporin, quinidine, dapsone, barbiturates, diazepam, verapamil, beta-adrenergic blockers, disopy-

Table 3. Major Adverse Reactions to Antituberculosis Agents*

Isoniazid	Hepatitis, peripheral neuritis, skin rashes, neurologic disturbances
Rifampin	Nausea, vomiting, abdominal cramps, diarrhea, hepatotoxicity, flu-like syndrome, renal failure, thrombocytopenia, hemolytic anemia, skin rashes, headache, drowsiness
Ethambutol	Retrobular neuritis
Pyrazinamide	Hepatitis, hyperuricemia, gout, arthralgia, skin rashes
Streptomycin	Ototoxicity, nephrotoxicity, transient giddiness, perioral paraesthesias, skin rashes
Para-amino salicylic acid	Anorexia, nausea, vomiting, diarrhea, skin rashes, hepatitis
Cycloserine	dizziness, headache, tremor, insomnia, slurred speech, depression, anxiety, psychosis, suicide attempts
Ethionamide	Nausea, vomiting, diarrhea, anorexia, excessive salivation, metallic taste in mouth, hepatitis, skin rashes, stomatitis, photosensitivity, goiter, acne, gynecomastia, impotence, peripheral neuropathy, arthralgia
Clofazamine	Brown pigmentation of skin, bowel obstruction, splenic infarction, gastrointestinal bleeding

*Adapted from Reference 5

ramide, theophylline, mexiletine, and chloramphenicol [rifampin product insert]. Concurrent administration of para-aminosalicylic acid may impair absorption of rifampin from the gastrointestinal tract.[13] Concurrent administration of isoniazid, rifampin, and ketoconazole can result in loss of therapeutic efficacy for all three drugs.[15]

A relatively trivial adverse effect of rifampin therapy is orange-colored staining of all body excretions and secretions (saliva, tears, urine, sweat, and feces). This can result in permanent staining of soft contact lenses and be difficult to remove from clothing. Patients should be advised to expect this effect.

Gastrointestinal disturbances are the most common additional adverse reaction to rifampin therapy. Nausea and vomiting occur in 1.5% of patients treated with rifampin, and may preclude further therapy.[8] Abdominal cramps and diarrhea also occur.

Hepatotoxicity also occurs with rifampin therapy. Elevations of serum transaminases have been observed transiently in many asymptomatic patients shortly after initiation of therapy; these tend to resolve as therapy continues.[13] The frequency of this adverse effect is higher in patients who inactivate this drug slowly, opposite the situation with isoniazid. Significant jaundice occurs in 0.6% of patients and is an indication for discontinuing therapy.[8] In patients taking both isoniazid and rifampin, a predominant increase in serum concentrations of alkaline phosphatase and bilirubin suggests rifampin-induced toxicity, whereas, a predominant increase in transaminases may be due to rifampin, isoniazid, or both.[8] Rifampin hepatotoxicity is generally considered reversible.

Intermittent therapy with ≥900 mg/day of rifampin or reinstitution of therapy after a drug-free interval has resulted in a syndrome characterized by a flu-like illness that may be complicated by renal failure, thrombocytopenia, and hemolytic anemia, and has been fatal. It is believed that the pathogenesis of this reaction is immunological

Other less common adverse reactions associated with rifampin therapy include interstitial nephritis, light chain cast nephropathy and acute renal failure, pure red cell aplasia, headache, and drowsiness.

For completeness, let's briefly discuss rifabutin (Mycobutin®, formerly ansamycin).[16] This is a new rifamycin derivative that is recently approved in the U.S.A. for prophylaxis of *Mycobacterium avium-intracellulare* infection in patients with AIDS. At present, there is inadequate information for recommendation of this agent in any setting in the treatment of tuberculosis. In animal models, rifabutin is more active against *M. tuberculosis* than is rifampin, and may have activity against some rifampin-resistant strains (perhaps about 30% of rifampin-resistant *M. tuberculosis* are sensitive to rifabutin). It appears that the side effect profile of rifabutin is similar to that of rifampin. Further study of this agent for treatment of tuberculosis is warranted.

Rifapentine is another rifamycin derivative currently in investigative trials. Its principal advantages over rifampin appear to be a longer serum half-life and somewhat greater in vitro activity against several species of Mycobacterium.[12]

Ethambutol

Ethambutol ([D-2,2'-(*eth*ylenedii*m*ino)di-1-*but*an*ol* dihydrochloride], Myambutol®) is a synthetic antimicrobial that is chemically unrelated to any other antimicrobial agent. Its exact mechanism of action is unknown, but it is probably an antimetabolite affecting RNA synthesis.[7] Resistance develops in a stepwise fashion when ethambutol is used without companion drugs. precluding this option. Ethambutol is virtually devoid of antimicrobial activity except that against mycobacteria.

Orally administered ethambutol is 75 to 80% absorbed. It is available only for oral administration. Therapeutic concentrations are achieved in the cerebrospinal fluid in the presence of meningeal inflammation. The majority of ethambutol is excreted unchanged in the urine; dosage reduction is recommended in the presence of renal insufficiency.[7]

The major toxicity of ethambutol therapy is neuropathy. Peripheral neuropathy may occur, but the most common serious adverse effect of ethambutol is retrobulbar neuritis. The incidence of retrobulbar neuritis is dose related: it occurs in perhaps 5% or fewer of patients treated with 25 mg/kg/d and its incidence is lower in those receiving 15 mg/kg/d.[8] Retrobulbar neuritis is manifested as impairment of visual acuity, loss of red/green color vision, central scotomas, or a peripheral field defect. It is usually reversible. All patients to receive ethambutol should be informed of this possible adverse reaction and advised to promptly report any visual changes. Patients to receive an extended course of 25 mg/kg/d probably should have monthly visual examinations. Because it is difficult to assess for visual changes in children less than 6 years of age, ethambutol is generally not recommended for this age group.

Other less common adverse reactions associated with ethambutol therapy include gastrointestinal disturbances, allergic reactions including rash, hyperuricemia due to decreased renal urate clearance, and thrombocytopenia.[8]

Pyrazinamide

Pyrazinamide is a synthetic antimicrobial that is the pyrazine analogue of nicotinamide. Its mechanism of action is unknown. Although its chemical structure is similar to that of isoniazid, its mechanism of action is different.[5] As is the case with all antituberculosis agents, resistance develops rapidly when pyrazinamide is used alone; therefore, it should never be used alone.

Pyrazinamide is well absorbed after oral administration, the only available form. Pyrazinamide diffuses well into all body tissues and fluids, including cerebrospinal fluid. Pyrazinamide is metabolized by the liver to the active metabolite, pyrazinoic acid, which is subsequently excreted by the kidneys.

A major toxicity of pyrazinamide is hepatotoxicity. Although initial reports of pyrazinamide hepatotoxicity estimated the incidence as around 15%, recent reports indicate that the incidence of hepatotoxicity in patients receiving isoniazid, rifampin, and pyrazinamide is 1 to 5%.[8] Pyrazinamide interferes with the excretion of uric acid by decreasing its tubular secretion. High serum uric acid concentrations may result. Acute gouty arthropathy is uncommon, but arthralgias are more frequent and do appear to be related to serum uric acid concentrations.[5] Both hepatotoxicity and hyperuricemia are dose related. Some believe that dosage reduction is indicated for severe hyperuricemia (serum uric acid >15 mg/dL). Less common adverse reactions of pyrazinamide therapy are skin rashes and gastrointestinal disturbances.

Pyrazinamide should be avoided in pregnant women because the available data on teratogenicity are inadequate. Isoniazid, rifampin, and ethambutol can be used in pregnant or lactating women.[17]

Streptomycin

Streptomycin is an aminoglycoside antibiotic and has been discussed as such earlier in this symposium.[18] Usual dosage for treatment of tuberculosis is presented in Table 2 and major adverse reactions are reviewed in Table 3. Toxicity to the eighth cranial nerve is cumulative and irreversible.

These five drugs comprise first-line therapy for tuberculosis. Most patients with new onset tuberculosis can be treated with an appropriate combination chemotherapy regimen employing first-line agents. In the next section, agents used as second-line antituberculosis agents will be briefly discussed, in order to establish basic familiarity with these agents. Dosages and common adverse reactions to the second-line antituberculosis agents are also presented in Tables 2 and 3.

Second-Line Agents

Para-aminosalicylic acid is a synthetic antimicrobial that inhibits the growth of *M. tuberculosis* by impairment of folate synthesis. Once a primary companion drug to isoniazid, its role in this regard has largely been supplanted. The major reason para-aminosalicylic acid has fallen into such disfavor is the common occurrence of gastrointestinal intolerance. This occurs so commonly and may be so severe as to be a major factor in patient noncompliance. Hypersensitivity reactions, including skin rashes, are fairly common with para-aminosalicylic acid therapy. Other adverse reactions associated with therapy with para-aminosalicylic acid are a drug-induced lupus-like syndrome, a mononucleosis-like syndrome, and toxic hepatitis.

Cycloserine is a broad-spectrum antibiotic produced by *Streptomyces orchidaceus.* It is now produced synthetically. The utility of cycloserine as an antibiotic and antituberculosis agent is reduced by its propensity to produce nervous system toxicity. Cycloserine therapy has been associated with a variety of behavioral changes and with seizures and also with peripheral neuropathy.

Ethionamide is a synthetic derivative of isonicotinic acid. It is well absorbed orally and distributes well to all body spaces, including cerebrospinal fluid. It is metabolized by the liver, with metabolites mainly excreted in the urine. Most patients taking ethionamide will experience gastrointestinal irritation with nausea and frequently vomiting, and this is the principle limitation of usefulness of ethionamide. This can be particularly unpleasant as the thiol group in ethionamide is released upon dissolution of the enteric-coated preparation and vomitus has the characteristic rotten eggs taste. Various neurologic disorders can be caused by ethionamide, including peripheral neuropathy and psychiatric disturbances; these may be alleviated by pyridoxine. Reversible hepatotoxicity may occur in up to 5% of patients receiving ethionamide.[7]

Capreomycin is a polypeptide antibiotic produced by *Streptomyces capreolus.* It is available only as an intramuscular injection. It has an incomplete cross-resistance pattern with the aminoglycosides, making it occasionally useful in patients resistant to aminoglycosides and other primary drugs. It displays similar pharmacokinetic properties to the aminoglycosides and has a similar toxicity profile.[5]

Viomycin is a structurally complex basic polypeptide antibiotic. It, too, is only available as an injectable form. It also has incomplete cross-resistance with the aminoglycosides, but fairly complete cross-resistance with capreomycin. Its toxicity is also primarily nephrotoxicity.

Other Agents Used

The aminoglycosides kanamycin and amikacin are also used as antituberculosis agents. The aminoglycosides have been reviewed earlier in this symposium.[18] Streptomycin, kanamycin, and amikacin have similar activity against *M. tuberculosis*[19]; streptomycin is favored because of the toxicity and expense of the others. The fluoroquinolones ciprofloxacin and ofloxacin have activity against several mycobacterial species, as discussed earlier in this symposium.[20] The same can be said for the recently introduced macrolide, clarithromycin.[21] At the present time, there is no routine indication for use of either a fluoroquinolone or clarithromycin for treatment of tuberculosis. It has also been noted earlier in this symposium that β-lactam/β-lactamase inhibitor antibiotics have some activity against several species of mycobacteria, including *M. tuberculosis.* Further evaluation is required before any role in antimycobacterial therapy can be ascribed to β-lactam/β-lactamase inhibitor antibiotics.

Clofazamine is a derivative of the aniline dyes, primarily developed as an antileprosy drug (i.e., used for treatment of infection due to *Mycobacterium leprae).* It has some activity against other species of Mycobacterium as well, and is a component of several combination regimens for treatment of *Mycobacterium avium-intracellulare* infections in patients with AIDS.[22] There is no current indication for routine usage of clofazamine for treatment of tuberculosis. The pharmacology of clofazamine is complex, but highlighted by a serum half-life of approximately 70 days and elimination primarily by biliary excretion.[7] The principal adverse effect of clofazime is skin discoloration ranging from red to purple to almost black; gastrointestinal intolerance can also occur.[7]

Basic Principles of Chemotherapy

An even modestly complete discourse on the principles of antituberculosis chemotherapy is more than we are willing to write, more than the editors are willing to publish, and more than you are willing to read. Rather, I will present the principles of treating initial uncomplicated tuberculosis and emphasize when these rules do not apply; in all such situations, expert consultation should be obtained.

But first, the importance of obtaining appropriate and adequate specimens for isolation of the infecting organism and for determination of drug susceptibility can not be overemphasized. Every effort should be made to assure the ultimate isolation of the organism before initiation of therapy, although therapy will usually be begun before the results of such tests are available. All isolates should be tested for susceptibility, at least to the primary antituberculosis agents. Efforts in the microbiology laboratory must be made to achieve optimal and rapid isolation, speciation, and susceptibility reporting. These are currently most quickly achieved by ^{14}C tracer detection of growth and gene probe speciation. Additionally, reporting of all cases and regional collation of drug susceptibility are imperative.

When considering the choice of an antituberculosis regimen, risk factors for drug-resistant infection must be evaluated. The following are some of these risk factors: (1) prior antituberculosis drug treatment; (2) contact with a previously treated individual or contact with a person with known or suspected multiply drug-resistant tuberculosis; (3) HIV infection or significant risk for HIV infection; (4) time spent in shelters, hospitals, or prisons, especially those in areas where multiply drug-resistant tuberculosis has been encountered; (5) recent emigration from an area with a high prevalence of primary resistance of *M. tuberculosis* to first line antituberculosis drugs, such as Asia, Africa, or Latin America; and (6) residence in geographic areas in the U.S.A. with a high prevalence of drug-resistant tuberculosis, such as southern Florida.[23] All patients with tuberculosis should undergo serologic testing for HIV infection. Treatment of patients with these risk factors for drug-resistant tuberculosis should be designed with expert consultation.

For patients with pulmonary tuberculosis without any of the above-detailed risk factors for drug-resistant tuberculosis, a specific treatment and monitoring plan should be developed within four days of diagnosis.[17] The preferred treatment regimen at last official recommendation[17] is a 6-month regimen that includes isoniazid, rifampin, and pyrazinamide daily for 2 months, followed by 4 months of daily or twice-weekly isoniazid and rifampin. An alternative regimen is 1 or 2 months of daily isoniazid and rifampin, followed by daily or twice-weekly isoniazid and rifampin for a total duration of 9 months. Dosages used in these regimens are presented in Table 2. Both of these regimens should be supplemented with either ethambutol or streptomycin if extensive or life-threatening disease is present. Both regimens assume identification of *M. tuberculosis* sensitive to the drugs employed. Neither of these regimens, however, adapts easily to directly observed therapy.

A regimen designed for directly observed therapy (DOT) and demonstrated to be efficacious, relatively nontoxic, and cost-effective is as follows.[24] For the first 2 weeks, patients receive daily isoniazid (300 mg), rifampin (600 mg), pyrazinamide (1.5 gm if ≤50 kg body

weight, 2.0 gm if 51 to 74 kg, 2.5 gm if ≥75 kg), and streptomycin (750 mg if ≤50 kg body weight, 1.0 gm if >50 kg). Then, for weeks 3 through 8, patients receive twice-weekly isoniazid (15 mg/kg), rifampin (600 mg), pyrazinamide (3.0 gm if ≤50 kg body weight, 3.5 gm if 51 to 74 kg, 4.0 gm if ≥75 kg) and streptomycin (1.0 gm if ≤50 kg body weight, 1.25 gm if 51 to 74 kg, 1.5 gm if ≥75 kg). Twice-weekly therapy also usually provides pyridoxine 100 mg twice weekly. Therapy is completed by twice-weekly therapy in weeks 9 through 26 with continuation of isoniazid and rifampin therapy. It is our opinion that this is the preferred regimen for DOT, and as already stated, DOT is greatly preferred.

Patients with a history of any prior drug treatment for tuberculosis should generally be treated with a regimen containing at least two new drugs. The DOT regimen detailed above is also acceptable for treatment of extrapulmonary tuberculosis. Special considerations in treatment of tuberculous meningitis provide an indication for expert consultation. Management of tuberculous meningitis has been recently reviewed.[25]

Treatment of infections due to mycobacteria other than *M. tuberculosis* has also been recently reviewed.[26] The management of infections due to these other mycobacteria often requires expert consultation.

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Laparoscopic Repair of Perforated Duodenal Ulcer by Graham Omentopexy

William C. Jennings, MD

A 72-year-old male patient presented through the emergency department with a 24-hour history of sudden, severe, and unrelenting abdominal pain. He reported a previous history of peptic ulcer. No significant history of alcohol ingestion was noted; however the patient has a long history of tobacco abuse. The patient was afebrile. His pulse 90 and BP 138/82. The abdomen was distended with board-like rigidity, guarding, and rebound. Signs of moderate dehydration were present. Abdominal films demonstrated free air within the abdomen.

After review with the patient of all surgical/medical options and treatment, he elected to undergo laparoscopic examination with consideration of surgical treatment by that method, if possible. The patient was found to have a typical perforated duodenal ulcer with continuous leakage and the expected marked abdominal inflammation. A full evaluation of the entire abdomen was accomplished without evidence of discrete loculated fluid or abscess. Complete peritoneal lavage was accomplished and a Graham closure of his duodenal ulcer completed by laparoscopic technique. During the recovery phase the patient had an anticipated ileus for approximately three days. It gradually resolved allowing discontinuation of NG suction and an advancement of diet. Barium swallow demonstrated the sealed perforation site (Fig. 1).

The patient's hospitalization was prolonged by an unrelated evaluation for a pulmonary nodule that was eventually determined to be benign. He remained well during a six-month follow-up with no gastrointestinal complaints. Medical treatment consists of H_2 blockers.

Operative Technique

The patient's abdomen was insufflated with the usual technique through a periumbilical incision that was utilized for placement of a 10 mm trocar and the laparoscope. Five-millimeter trocars were placed in the right upper quadrant and to the left of the midline under direct visualization. A typical duodenal ulcer could be easily identified with continuous spillage and no adhesions from adjacent soft tissue (Fig. 2). Full exploration of the abdomen was then accomplished, positioning the patient in different ways to allow in-



Figure 1. Barium study demonstrating sealed duodenal ulcer following Graham closure (omentopexy).

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spection through bowel loops and pelvis. All areas were copiously irrigated and meticulously aspirated of fluid (Fig. 3). A generous portion of the greater omentum could be easily positioned over the ulcer without tension. Suturing was considered; however, the omentum was easily secured to adjacent soft tissue and lesser omentum, using multiple metal clips without tension, and noted to be secure. No further soilage could be identified, and the laparoscopic procedure terminated without incident.

Discussion

Operative evaluation, lavage, and Graham closure (omentopexy) of perforated duodenal ulcer remains the most common treatment for this disease in the United States. Perforated duodenal ulcer has been treated nonoperatively with some success[1] but this approach is much more common in Europe than the United States. Laparoscopic treatment of perforated peptic ulcer has been reported by French surgeons in five patients[2] and in other case reports.[3] Debate centers on those patients found with early perforation and a history of chronic ulcer disease for providing a definitive procedure at time of operation.[4,5]

The Graham closure technique was appropriate in this patient with a prolonged history of soilage, the observed degree of spillage, and tissue inflammation noted at time of surgery. Lavage and suction irrigation of the abdomen was felt to be very good, as was the ability to examine the mid-abdomen and pelvis. New high-volume irrigation suction devices should make this process even faster. Laparoscopic suturing instruments, suturing techniques, new metal staple application devices, and other technical advances will enlarge the options available for surgical treatment of ulcer disease. This patient clearly benefitted by shortened recovery and likely had less pulmonary embarrassment than he would have had if treated by laparotomy.



Figure 2. Typical perforated anterior duodenal ulcer noted prior to laparoscopic closure.



Figure 3. Irrigation/suction abdominal lavage carried out in all quadrants.

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COMMENTARY

But Who Will Guard the Guardians Themselves?

Jack P. Enos, MD

This opinion piece examines whether or not the Oklahoma State Board of Medical Licensure and Supervision, as currently constituted and operating, does in fact contribute to "good" medical practice. The author, who has been interviewed by the board, has in turn made a study of the board and its methods, as well as interviewing other "disciplinees." This commentary is the opinion of one physician who felt compelled to write, even at the risk of some embarrassment.

"Sed quis custodiet ipsos custodes?"
—Juvenal

AFTER MORE THAN 36 YEARS OF WHAT I considered good medical practice (no malpractice suits or threats, many lovely babies, many satisfied patients, etc.), I was "invited" to appear before the Oklahoma State Board of Medical Examiners [now the Board of Medical Licensure and Supervision] to answer charges of prescribing Class III controlled substances in a manner not in keeping with the highest standards of the medical profession. These "charges" were instigated by a hard-core addict who used the falsified ploy of having a crippled and dying father, confined to a wheelchair by pain, requiring large amounts of controlled substances. When the story collapsed, it became apparent that he would be arrested and I was to be a witness for the prosecution; he subsequently fled the jurisdiction of the state of Oklahoma. Whatever befell him, I know not.

Be that as it may, I appeared before the board on January 22, 1988. The appearance got off to a ludicrous start. At the onset, the lawyer for the board took me aside and said, "Doctor, we have a problem. The physician who ordinarily states that a number of prescriptions (compiled by a pharmacist investigator) constitutes excessive use, stated he would not be able to testify against you as he feels you are a fine doctor. Would you, in the interest of time, be willing to stipulate that the use 'seems' excessive?" I replied, "I'm sure a physician could be found who might feel that way."

Proceeding to the hearing room, I was now asked if I wished to be represented by counsel, to which I stupidly replied, "If the time has come that the medical profession needs the legal profession to tell it how to practice medicine, we are in dire straits." The proceedings were brief, friendly, and interesting (see below) and I left chastened but not deeply steeped in guilt.

The next step was an appearance on March 28, 1989, before the Oklahoma State Board of Narcotics and Dangerous Drugs (BNDD). This appearance was more comfortable and the assembled group seemed to have no agenda of "he must be guilty—he's here!" The lawyer advising the board stated that she saw no cause for action and felt nothing had occurred that was contrary to the BNDD regulations. I left that

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very evening to go to the mountains to let the wind blow through my soul, feeling I had been exonerated.

Imagine my surprise a few days after my return when I received a registered letter from the BNDD. They felt appropriate action would be the suspension of my state narcotic permit for 48 hours (from Friday at midnight to Sunday at midnight!), three-year supervision with duplicate prescriptions, and a moderate fee to cover supervisory costs.

A year flew by and all requirements were met. After this year, I reappeared before the Board of Medical Examiners requesting remittal of the last two years of supervision. This was granted unanimously, and soon after I received a legal document confirming all penalties were forgiven and "held as naught." What a lovely phrase, except to this day my Oklahoma narcotic license continues to show PDA*! (Do you remember Hester Prynne and the scarlet letter?)

Anyway, we now look at the Board of Medical Examiners (and I venture to say I've studied them more than they did me). The State of Oklahoma is Number One in imposing discipline and the State of Massachusetts is Number Fifty. I feel they should both be mildly ashamed. The head of operations of the Board of Medical Examiners has since changed, and the effect on board methodology is clouded.

Also, a dear, proud, gracious MD friend of mine from a southern Oklahoma city had been disciplined by the board before I was, and his "fault" had been prescribing appetite suppressants to obese ladies. This authentic physician told me later how meticulous he had been in keeping records of weights, blood pressure, etc., but was disciplined by this same august body. Incidentally, he did have an attorney, and perhaps was disciplined to show that no one is above the law.

If any good thing has developed from all this, it seems to me the board has had less pejorative passion. Early on, they published a bulletin to be circulated among medical practitioners—I suppose to shed the clear light of justice on the malefactors. It died after a short life (out of kindness, I hope). Later, under another secretary, the personal confrontation concept was started where the presumed "bad apple" would be invited to meet head to head with the secretary or chairman to determine if formal proceedings were necessary.

I applaud the idea of personal confrontation highly. Many of the disciplinees to whom I've spoken seemed to be psychiatrists who felt the benzodiazepines were a good tool for phobias and anxieties, and the dosage and duration for therapy seemed quite correct to them.

In retrospect after five years, of my five patients whose charts were "called up for review," one male was lost to follow up; three females continue to see me, still using their Class III pain or anxiety medications in lesser amounts.

The other man, a real mensch, a Vietnam veteran working daily, leading a satisfying life (at least to him and his lawyer wife), and controlling his post traumatic stress disorder with two daily beers plus some Empirin #3, died as a "prescription drug overdose," which I believe was without suicidal intention. Though the cause of death was determined by the chief medical examiner, I signed the death certificate as his friend, physician, and the local medical examiner. He was responsible for his own life, and I do not blame the board for his death—only myself for not having the courage to stand up for what I know to be right. The findings, I feel, should have been appealed as the mechanism for doing so exists.

This had to be written by someone who has met the board, not some esoteric professor of pharmacology, or even the head of the Department of Psychiatry. This should probably have been written five years ago, and would have been, had I guts enough, and more time.

I have been, once again, invited to see the board. I hope to show that this is not merely a pill-counting contest, but that a competent physician may run afoul to the regulations.

I have asked several of my colleagues, of impeccable reputation, to contest their 'witness' and have asked a competent attorney to witness the proceedings and,if unfairness or mistakes occur, to then appeal their findings. At age 74, retirement might be the more appealing course, but not the more honorable.

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AMA PHOTO BY TED [illegible]

Remarks of the First Lady to the American Medical Association

MRS. CLINTON: THANK YOU VERY MUCH, MR. Speaker; all of the members of the House of Delegates, the officers and trustees of the AMA, and all whom you represent. It is an honor for me to be with you at this meeting and to have the opportunity to participate with you in an ongoing conversation about our health care system and the kinds of constructive changes that we all wish to see brought to it.

I know that you have, through Health Access America and through other activities and programs of the AMA, been deeply involved in this conversation already, and all of us are grateful for your contribution. I'm also pleased that you invited students from the Nathan Davis Elementary School to join us here this afternoon. I know that the AMA has a special relationship with this school, named as it is for the founder of the AMA, and that the AMA participates in its corporate capacity in the Adopt-a-School program here in Chicago. You have made a real contribution to these young men and women. And not only have you provided free immunizations and physicals and lectures and help about health and related matters, but you have served as role models and mentors. It is very important that all of us as adults do what we can to give young people the skills they will need to become responsible and successful adults. And I congratulate you for your efforts and welcome the students here today.

All of us respond to children. We want to nurture them so they can dream the dreams that free and healthy children should have. This is our primary responsibility as adults. And it is our primary responsibility as a government. We should stand behind families, teachers and others who work with the young, so that we can enable them to meet their own needs by becoming self sufficient and responsible so that they, in turn, will be able to meet their families and their own children's needs.

When I was growing up, not far from where

In Chicago on June 13, Hillary Rodham Clinton spoke to the AMA House of Delegates about health care reform. This transcript of her remarks was provided to the JOURNAL by the White House Office of Media Affairs, Washington, D.C.

we are today, this seemed an easier task. There seemed to be more strong families. There seemed to be safer neighborhoods. There seemed to be an outlook of caring and cooperation among adults that stood for and behind children. I remember so well my father saying to me that if you get in trouble at school, you get in trouble at home—no questions asked—because there was this sense among the adult community that all of them, from my child's perspective, were involved in helping their own and others' children.

Much has changed since those days. We have lost some of the hope and optimism of that earlier time. Today, we too often meet our greatest challenges, whether it is the raising of children or reforming the health care system, with a sense that our problems have grown too large and unmanageable. And I don't need to tell you that kind of attitude begins to undermine one's sense of hope, optimism, and even competence.

We know now—and you know better than I—that over the last decade our health care system has been under extraordinary stress. It is one of the many institutions in our society that has experienced such stress. That stress has begun to break down many of the relationships that should stand at the core of the health care system. That breakdown has, in turn, undermined your profession in many ways, changing the nature of and the rewards of practicing medicine.

Preventive care

■ We believe strongly that we have to emphasize preventive care. And ... provide a basic policy of preventive care. And ... be sure that all of you and those who come after you into medicine are trained well ... to appreciate the importance of preventive care....

■ We need to be a system that does not take care of the sick but instead promotes health wherever we can....

Canadian system?

■ We have looked at every other system in the world.... We have concluded that what is needed is an American solution for an American problem by creating an American health care system that works for America.

Most doctors and other health care professionals choose careers in health and medicine because they want to help people. But too often because our system isn't working and we haven't taken full responsibility for fixing it, that motive is clouded by perceptions that doctors aren't the same as they used to be. They're not really doing what they used to do. They don't really care like they once did.

You know and I know that we have to work harder to renew a trust in who doctors are and what doctors do. That is also not unique to the medical community. Just as our institutions across society are under attack and stress, all elements of those institutions are finding that they no longer can command the trust and respect, whether we talk of parents or government officials or other professionals—police officers, teachers—that should come with giving of themselves and doing a job well that needs to be done.

BUT FOCUSING THIS AFTERNOON ON THOSE concerns that are yours—what has happened with medicine, what is likely to happen—we need to start with a fundamental commitment to making the practice of medicine again a visible, honored link in our efforts to promote the common good. And the way to do that is to improve the entire system of which you are a part. We cannot create the atmosphere of trust and respect and professionalism that you deserve to have, and that many of you who are in this room remember from earlier years, without changing the incentives and the way the entire system operates. That has to be our primary commitment. If we do not put medicine and those who operate within medicine in the forefront of the respect they deserve to have, no matter what we do to the system on the margins will not make the differences that it should.

As you know, the President is in the process of finalizing his proposal for health care reform, and I am grateful to speak with you about that process and where it is today and where it is going. I had originally hoped to join you at your meeting in March in Washington, D.C. And I, again, want to apologize for my absence. I very much appreciated Vice President Gore attending for me, and I also appreciated the kind words from your executive officials on behalf of the entire association because of my absence.

My father was ill and I spent several weeks with him in the hospital before he died. During his hospitalization at St. Vincent's Hospital in Little Rock, Arkansas, I witnessed firsthand the courage and commitment of health care professionals, both directly and indirectly. I will always appreciate the sensitivity and the skills they showed, not just in caring for my father, not just in caring for his family—which, as you know, often needs as much care as the patient, but in caring for the many others whose names I will never know. I know that some of you worry about what the impact of health care reform will be on your profession and on your practice.

Let me say from the start, if I read only what the newspapers have said about what we are doing in our plan, I'd probably be a little afraid myself, too, because it is very difficult to get out what is going on in such a complex process.

But the simple fact is this: The President has asked all of us, representatives of the AMA, of every other element of the health care system, as well as the administration, to work on making changes where they are needed, to keeping and improving those things that work, and to preserving and conserving the best parts of our system as we try to improve and change those that are not.

This system is not working as well as it did, or as well as it could—for you, for the private sector, for the public or for the nation. The one area that is so important to be understood on a macronational level is how our failure to deal with the health care system and its financial demands is at the center of our problems financially in Washington. Because we cannot control health care costs and become further and further behind in our efforts to do so, we find our economy, and particularly the federal budget, under increasing pressure.

Just as it would be irresponsible, therefore, to change what is working in the health care system, it is equally irresponsible for us not to fix what we know is no longer working. So let us start with some basic principles that are remarkably like the ones that you have adopted in your statements, and in particularly in Health Access America. We must guarantee all Americans access to a comprehensive package of benefits, no matter where they work, where they live, or whether they have ever been sick before. If we do not reach universal access, we cannot deal with our other problems.

AND THAT IS A POINT THAT YOU UNDERSTAND that you have to help the rest of the country understand—that until we do provide security for every American when it comes to health we cannot fix what is wrong with the health care system. Secondly, we do have to control costs. How we do that is the great challenge in this system, but one thing we can agree on is that we have to cut down on the paperwork and the bureaucracy in both the public and private sectors.

We also have to be sure that when we look at costs, we look at it not just from a financial perspective, but also from a human perspective. I remember sitting in the family waiting area of St. Vincent's, talking to a number of my physician friends to see how we were doing. And one day, one of my friends told me that, every day, he discharges patients who need medication to stabilize a condition. And at least once a day, he knows there is a patient who will not be able to afford the prescription drugs he has prescribed, with the result that that patient may decide not to fill the prescription when the hospital supply runs out. Or that patient may decide that even though the doctor told him to take three pills a day, he'll just take one a day so it can be stretched further.

And even though St. Vincent's has created a fund to try to help support the needs of patients who cannot afford prescriptions, there's not enough to go around, and so every day there is someone who my friend knows and you know will be back in the hospital because of their inability either to afford the care that is required after they leave, or because they try to cut the corners on it, with the net result that then you and I will pay more for that person who is back in the hospital than we would have if we had taken a sensible approach toward what the real costs in the medical system are. That is why we will try, for example, to include prescription drugs in the comprehensive benefit package for all Americans, including those over 65, through Medicare.

We believe that if we help control costs up front, we will save costs on the back end. That is a principle that runs through our proposal and which each of you knows from firsthand experience is more likely to be efficient in both human and financial terms. We will also preserve what is best in the American health care system today.

We have looked at every other system in the

Bureaucracy

- The erosion of the doctor/patient relationship is only one piece of the problem. Another piece is the role that insurance companies have come to play and the role that the government has come to play along with them in second-guessing medical decisions....
- The result of ... excessive oversight ... is a system of backward incentives. It rewards providers for overprescribing, overtesting, and generally overdoing. And worse, it punishes doctors who show proper restraint and exercise their professional judgment in ways that those sitting at the computers disagree with....
- There is no master checklist that can be administered by some faceless bureaucrat that can tell you what you need to do on an hourly basis to take care of your patients; and, frankly, I wouldn't want to be one of your patients if there were....
- Blanketing an entire profession with rules aimed at catching those who are not living up to their professional standards does not improve quality.... You are the ones who can tell better than I or better than some bureaucrat whether the quality of medicine that is being practiced in your clinic, in your hospital, is what you would want for yourself and your family....
- We have to simplify and eliminate the burdensome regulations created under CLIA....

world. We have tried to talk to every expert whom we can find to describe how any other country tries to provide health care. And we have concluded that what is needed is an American solution for an American problem by creating an American health care system that works for America. And two of the principles that underlie that American solution are quality and choice.



We want to ensure and enhance quality. And in order to do that, we're going to have to make some changes, and you know that. We cannot, for example, promise to really achieve universal access if we do not expand our supply of primary care physicians, and we must do that. And you will have to help us determine the best way to go about achieving that goal.

I've spoken with representatives of our medical schools, and we have talked about how the funding of graduate medical education will have to be changed to provide incentives for the training of more primary care physicians. I have talked with representatives of many of the associations, such as this one, about how continuing educational opportunities could help even mid-career physicians, once we have a real supply of primary care physicians who are adequately reimbursed and adequately supported, how they might even go back into primary care.

We have also very much put choice in the center of our system so that we will have not just choice for patients as to which plan they choose to join, but choice for physicians as to which plan they choose to practice with, including the option of being part of more than one plan at the same time.

Now, as we work out all of the details in the many proposals and its parts that must come together, I am not suggesting that you will agree with every recommendation the President makes. I don't expect any group to do that. In fact, I suppose that if everybody's not a little put out that means we probably haven't done it right. But I do hope and expect that this group, as with other groups representing physicians and nurses and other health care professionals will find in this plan much to be applauded and supported. And I also believe that given the complexities of the problem we face, it would be difficult to arrive at a solution that was universally accepted.

But the reason I have confidence that this house, the AMA, and others will be supportive of the President's proposal is because we have benefited so much from what you have already done and from the involvement of many of you and others around the country.

Again, contrary to what you may have heard, scores of practicing physicians served on the working groups that were studying health care reform. I am deeply grateful on a personal level that members of the AMA's leadership spent invaluable time coming to meeting after meeting, day after day sharing their ideas, reacting to ideas at the White House. And, of course, in the course of that we learned we had many common goals and objectives.

We will not only stand for universal coverage, but in addition the following: community rating so that we can assure all Americans they will be taken care of; eliminating restrictions based on preexisting conditions so that every American will be eligible; a nationally guaranteed comprehensive benefits package that will emphasize primary and preventive health care as well as hospitalization and other care; and the kind of choice and quality assurances that we will need to have to make sure this new system not only operates well during the transition but gets a firm footing as it moves into the future and we will therefore be emphasizing more on practice parameters and outcomes research so that you, too, can know better what works.

One of the great interesting experiences I have had during the past months is as I've traveled around from state to state is having doctors coming up to me and telling me that they need more information; that all too often the information they receive doesn't come to them in forms that they believe are practical in their particular context. And what we want to do is by working with organizations like yours is be

A legacy

■ We can make a difference now that will be a legacy for all of you. We can once again give you the confidence to say to your grandsons and granddaughters, yes, do go into medicine; yes, it is the most rewarding profession there is.

sure that the quality outcomes and the kind of research that will done will be readily available to every practicing physician in the country.

We also believe that it will be essential to continue medical research and to use the breakthroughs in medical research, again, not just to alleviate human suffering but to save money, because you know better than I that often times a breakthrough in research, a new drug, a new procedure is the quickest way to take care of the most people in a cost-effective manner. So we will continue to support medical research.

ALL OF THESE PRINCIPLES ARISE FROM THE same common assumption—that the status quo is unacceptable. And it is not really even any longer a status quo because we do not stand still, we drift backwards. Every month people lose their insurance; every month you have more micromanagement and regulation to put up with; every month our health care system becomes more expensive to fix.

I know that many of you feel that as doctors you are under siege in the current system. And I think there is cause for you to believe that, because we are witnessing a disturbing assault on the doctor/patient relationship. More and more employers are buying into managed care plans that force employees to choose from a specific pool of doctors. And too often, even when a doctor is willing to join a new plan to maintain his relationship with patients, he, or she I should say, is frozen out.

What we want to see is a system in which the employer does not make the choice as to what plan is available for the employee, the employee makes that choice for him or herself. But if we do not change and if the present pattern continues, as it will if we do not act quickly, the art of practicing medicine will be forever transformed. Gone will be the patient's treasured privilege to choose his or her doctor. Gone will be the close trusting bonds built up between physicians and patients over the years. Gone will be the security of knowing you can switch jobs and still visit your longtime internist or pediatrician or OB/GYN

We cannot afford to let that happen. But the erosion of the doctor/patient relationship is only one piece of the problem. Another piece is the role that insurance companies have come to play and the role that the government has come to play along with them in second-guessing medical decisions.

I can understand how many of you must feel. When instead of being trusted for your expertise, you're expected to call an 800 number and get approval for even basic medical procedures from a total stranger.

Frankly, despite my best efforts of the last month to understand every aspect of the health care system, it is and remains a mystery to me how a person sitting at a computer in some air-conditioned office thousands of miles away can make a judgment about what should or shouldn't happen at a patient's bedside in Illinois or Georgia or California. The result of this excessive oversight, this peering over all of your shoulders is a system of backward incentives. It rewards providers for overprescribing, overtesting, and generally overdoing. And worse, it punishes doctors who show proper restraint and exercise their professional judgment in ways that those sitting at the computers disagree with.

Dr. Bob Barrinson, one of the practicing physicians who spent hours and hours working with us while also maintaining his practice, told us recently of an experience that he had as one of many. He admitted an emergency room patient named Jeff. Jeff suffered from cirrhosis of the liver and ascites. Dr. Barrinson put him in the hospital and within 24 hours received a call from Jeff's insurance company. The insurance company wanted to know exactly how many days Jeff would be in the hospital and why. Dr. Barrinson replied that he couldn't predict the precise length of stay. A few days later the insurance company called back and questioned whether Jeff would need surgery. Again, Dr. Barrinson said he wasn't yet sure.

And what was Dr. Barrinson's reward for his honesty and his professionalism? He was placed on the insurance company's "special exceptions" list. You know, that's a list of troublesome doctors who make the insurance company wait a few days or a few weeks to determine the bottom line on a particular patient.

From that point on, the insurance company called Dr. Barrinson six times in two weeks. Each time he had to be summoned away from the patient to take the call. Each time he spoke

Tort reform

- We will offer a serious proposal to curb malpractice problems for all of you.... But ... in order to do that ... we must have organized medicine standing ready to say we will do a better job of taking care of the problems within us....
- We will propose serious malpractice reform, and we will have to look to you to help us make sure that the problems that will still flow from people who should not be making decisions will be eliminated....
- Moving it through the Congress is not going to be easy....

to a different insurance company representative. Each time he repeated the same story. Each time his role as the physician was subverted. And each time the treatment of the patient was impeded.

Dr. Barrinson and you know that medicine, the art of healing, doesn't work like that. There is no master checklist that can be administered by some faceless bureaucrat that can tell you what you need to do on an hourly basis to take care of your patients; and, frankly, I wouldn't want to be one of your patients if there were.

Now, adding to these difficulties doctors and hospitals and nurses, particularly, are being buried under an avalanche of paperwork. There are mountains of forms, mountains of rules, mountains of hours spent on administrative minutiae instead of caring for the sick. Where, you might ask yourself, did all this bureaucracy come from? And the short answer is, basically, everywhere.

There are forms to ensure appropriate care for the sick and the dying; forms to guard against unnecessary tests and procedures. And from each insurance company and government agency there are forms to record the decisions of doctors and nurses. I remember going to Boston and having a physician bring into a hearing I held there the stack of forms his office is required to fill out. And he held up a Medicare form and next to it he held up an insurance company form. And he said that they are the same forms that ask the same questions, but the insurance company form will not be accepted by the government, and the government form will not be accepted by the insurance company. And the insurance company basically took the government form, changed the title to call it by its own name and requires them to have it filled out. That was the tip of the iceberg.

Choice

- We will have not just choice for patients as to which plan they choose to join, but choice for physicians as to which plan they choose to practice with, including the option of being part of more than one plan at the same time.
- What we want to see is a system in which the employer does not make the choice as to what plan is available for the employee, the employee makes that choice for him or herself.... If we do not change ... gone will be the patient's treasured privilege to choose his or her doctor....

One nurse told me that she entered the profession because she wanted to care for people. She said that if she had wanted to be an accountant, she would have gone to work for an accounting company instead. But she, like many other nurses, and as you know so well, many of the people in offices now, are required to be bookkeepers and accountants, clinicians, not caregivers.

The latest statistic I have seen is that for every doctor a hospital hires, four new administrative staff are hired. And that in the average doctor's office 80 hours a month is now spent on administration. That is not time spent with a patient recovering from bypass surgery or with a child or teenager who needs a checkup and maybe a little extra TLC time of listening and counseling, and certainly not spent with a patient who has to run in quickly for some kind of an emergency.

BLANKETING AN ENTIRE PROFESSION WITH rules aimed at catching those who are not living up to their professional standards does not improve quality. What we need is a new bargain. We need to remove from the vast majority of physicians these unnecessary, repetitive, often even unread forms and instead substitute for what they were attempting to do—more discipline, more peer review, more careful scrutiny of your colleagues. You are the ones who can tell better than I or better than some bureaucrat whether the quality of medicine that is being practiced in your clinic, in your hospital, is what you would want for yourself and your family.

Let us remove the kind of micromanagement and regulation that has not improved quality and has wasted billions of dollars. But then you have to help us substitute for it a system that the patients of this country, the public of this country, the decision-makers of this country can have confidence in. Now, I know there are legal obstacles for your being able to do that, and we are looking very closely at how we can remove those so that you can be part of creating a new solution in which everyone, including yourself, can believe in.

In every private conversation I've had with a physician, whether it's someone I knew from St. Vincent's or someone I had just met, I have asked: Tell me, have you ever practiced with or around someone you did not think was living up to your standards? And, invariably, the answer is, well, yes, I remember in my training; well, yes, I remember this emergency room work I used to do; yes, I remember in the hospital when so-and-so had that problem. And I've said, do you believe enough was done by the profession to deal with that problem and to eliminate it? And, invariably, no matter who the doctor is, I've been told, no, I don't.

We want you to have the chance so that in the future you can say, yes, I do believe we've been dealing with our problems. It is not something we should leave for the government, and, certainly, we cannot leave it to the patient. That is the new kind of relationship I think that we need to have.

Finally, if we do not, as I said earlier, provide universal coverage, we cannot do any of what I have just been speaking about because we cannot fulfill our basic commitment you as physicians, us as a society, that we will care for one another. It should no longer be left to the individual doctor to decide to probe his conscience before determining whether to treat a needy patient. I cannot tell you what it is like for me to travel around to hear stories from doctors and patients that are right on point.

But the most poignant that I tell because it struck me so personally was of the woman with no insurance; working for a company in New Orleans; had worked there for a number of years; tried to take good care of herself; went for the annual physical every year; and I sat with her on a folding chair in the loading dock of her company along with others—all of whom were uninsured; all of whom had worked numbers of years—while she told me at her last physical her doctor had found a lump in her breast and referred her to a surgeon. And the surgeon told her that if she had insurance, he would have biopsied it but because she did not he would watch it.

I don't think you have to be a woman to feel what I felt when that woman told me that story. And I don't think you have to be a physician to feel what you felt when you heard that story. We need to create a system in which no one ever has to say that for good cause or bad, and no one has to hear it ever again.

If we move toward universal coverage, so therefore everyone has a payment stream behind them to be able to come into your office, to be able to come into the hospital, you will again be able to make decisions that should be made with clinical autonomy, with professional judgment. And we intend to try to give you the time and free you up from other conditions to be able to do that.

One specific issue I want to mention, because I feel strongly about it—if my husband had not asked me to do this, I would have felt strongly about it because of the impact in my state of Arkansas—we have to simplify and eliminate the burdensome regulations created under CLIA—a well-intentioned law with many unintended consequences that have affected not only those of you in private practice but public health departments like ours in Arkansas around the country.

But again we need that new bargain. You have to help us know what should be eliminated so that we then can just focus in on a very small part of this whole situation and eliminate the rest of the regulations that were thrown on top.

So those are the kinds of issues in which we think we can make it more possible for you to practice in a more efficient, humane, better manner. We also believe strongly that we have to emphasize preventive care. And we have to provide a basic policy of preventive care. And we have to be sure that all of you and those who come after you into medicine are trained well in medical school to appreciate the importance of preventive care.


AMA PHOTO By T.L. GRUDZIN, JR.

Responsibility

■ The time has come for all of us, not just with respect to health care, but with respect to all of the difficulties our country faces, to stop walking away and to start stepping up and taking responsiblity.

Much of what is now considered outside the scope of mainstream medicine is crowding in. Many of us in this room, I know, exercise, try to watch our diets, do things to try to remain healthier. And yet often medical education and medicine as it's practiced does not include those new kind of common-sense approaches to health. We need to be a system that does not take care of the sick but instead promotes health wherever we can in whatever way we possibly can do it.

And finally, let me say that we will offer a serious proposal to curb malpractice problems for all of you. But let me add that it, too, must be part of this new contract. In order to do that and to do it in a way that engenders the confi-

dence of the average American, we must have organized medicine standing ready to say we will do a better job of taking care of the problems within us. I have read or tried to read everything I can find about all of this. And you know as well as I do there are studies all over the field. It depends upon who writes it and who it's written for and the like. But we know there's a problem. We know we're going to deal with it. But one of the stark statistics from these studies is that all too often the largest number of malpractice suits is brought against the same physicians on a repetitive basis.

Universal access

■ We cannot ... promise to really achieve universal access if we do not expand our supply of primary care physicians, and we must do that....

■ If we do not ... provide universal coverage, we cannot do any of what I have just been speaking about because we cannot fulfill our basic commitment ... that we will care for one another. It should no longer be left to the individual doctor to decide to probe his conscience before determining whether to treat a needy patient....

And more...

■ We will not only stand for universal coverage, but in addition the following: community rating so that we can assure all Americans they will be taken care of; eliminating restrictions based on preexisting conditions so that every American will be eligible; a nationally guaranteed comprehensive benefits package that will emphasize primary and preventive health care as well as hospitalization and other care; the kind of choice and quality assurances that we will need to have ... and we will be emphasizing more on practice parameters and outcomes research....

Now, it may be that for some that is an unfair accusation, and we need to deal with that through reform. But for others, you need to weed them out of your profession if they cannot practice to the quality that you expect your fellow colleagues to practice to. So we will propose serious malpractice reform, and we will have to look to you to help us make sure that the problems that will still flow from people who should not be making decisions will be eliminated. That way we can give confidence back to you as a profession, that you will not be second-guessed or unfairly called into court. And we will give confidence to the public that they will be protected insofar as humanly possible. So that is what we will have to look for when we come forward with that.

Now, reaching consensus on all that should be done and putting it into a piece of legislation and moving it through the Congress is not going to be easy. There will be many groups that will nibble at the edges of it, not like the whole idea of it, want to continue to the status quo. But if we do not have the courage to change now, if we do not move toward a system that once again gives you back your professionalism to practice prudent, practical, intelligent medicine again; if we do not move toward restoring the dignity again to the doctor-patient relationship, and that encourages young people to become physicians because they want to participate in that wonderful process of healing and caring, then the entire society, but most particularly medicine, will suffer.

The reason we are doing any of this is because of children like those who are here from Nathan Davis. Most of us in this room are at least halfway through. And most of us in this room have sat in dozens and dozens of meetings just like this. We've sat and listened to people tell us what was wrong with health care or what medicine or with whatever, and we've talked about the problems at least seriously since the 1970s. And we've produced proposals like yours for Health Access America.

But while we have talked, our problems have gotten worse, and the frustration on the part of all of you and others has increased. Time and again, groups, individuals, and particularly the government, has walked up to trying to reform health care and then walked away.

There's enough blame to go around; every kind of political stripes can be included. But the point now is that we could have done something about health care reform 20 years ago and solved our problems for millions of dollars, and we walked away. Later we could have done something and solved our problems for hundreds of millions, and we walked away.

After 20 years, with the rate of medical inflation going up and with all of the problems you know so well, it is a harder and more difficult solution that confronts us. But I believe that if one looks at what is at stake, we are not talking just about reforming the way we finance health care, we are not talking just about the particulars of how we deliver health care, we are talking about creating a new sense of community and caring in this country in which we once again value your contribution, value the dignity of all people.

How many more meetings do we need? How many alerts? How many more plans? How many more brochures? The time has come for all of us, not just with respect to health care, but with respect to all of the difficulties our country faces to stop walking away and to start stepping up and taking responsibility. We are supposed to be the ones to lead for our children and our grandchildren. And the way we have be-

haved in the last years, we have run away and abdicated that responsibility. And at the core of the human experience is responsibility for children to leave them a better world than the one we found.

WE CAN DO THAT WITH HEALTH CARE. We can make a difference now that will be a legacy for all of you. We can once again give you the confidence to say to your grandsons and granddaughters, yes, do go into medicine; yes, it is the most rewarding profession there is.

So let's celebrate your profession by improving health care. Let's celebrate our children by reforming this system. Let's come together not as liberals or conservatives or Republicans or Democrats, but as Americans who want the best for their country and know we can no longer wait to get about the business of providing it. Thank you all very much.

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As a PLICO trustee since its inception and a former chairman of the claims committee, John McIntyre has played a major role in the company's success. Today, as president and chairman of the board, he is even more important to PLICO.

Story by Richard Green
Photography by Robert Taylor

TRYON IS A BLIP ON HIGHWAY 105 as it runs laterally through Lincoln County. But the town is also the hub of civilization between Carney, Perkins, and Agra. A few stores and churches surrounded by several houses surrounded by miles of farmland.

Although its size and population are small and amenities are exceedingly modest, Tryon has changed little in the last half century. There used to be a high school and a movie theater, but the schools thereabouts have been consolidated and the last picture show played years ago.

Perhaps the biggest change in the last 50 years has been in the residents' mobility and access to information. In the twenties and thirties, Tryon was almost like an outpost on the frontier; the people were isolated, and the focus of their lives was narrow and virtually unchanging. They had few plans, fewer prospects, and one universal goal: survival.

And though this relative seclusion was a handicap in some ways, it also was an invaluable asset to boys like John McIntyre because he was among people who esteemed sincerity, integrity, and the value of hard work. When he left Tryon after graduation from high school, those virtues were part of him, and although the whole man was far from formed, the foundation for his success as a leader in medicine was firmly established.

* * *

BY THE TIME JOHN CAME along on October 5, 1916, the McIntyres had lived in the Tryon area for nearly two

generations. The progenitor was a "bog-trotting Irishman" (meaning common) who immigrated to the U.S. in time to fight in the Civil War. He later married and homesteaded in what was to become Lincoln County, Oklahoma.

The McIntyres had two sons, Eugene and Benjamin. The boys attended a country school through the eighth grade and then, as was the norm in those days, dropped out to go to work. Within two or three years, their father died, probably from tuberculosis. When they were in their late teenage years, their mother remarried and moved away.

Gene married Lula McIntyre in 1914. Her family had come to Lincoln County by covered wagon in 1905. Although she was a farm girl, and Gene had been a homesteader's son, he and Lula never lived off the land. They lived in Tryon and started almost immediately trying to have their own family. Their first child, a daughter, was stillborn. Then they had two sons, John and Ray, born six years apart.

During the early twenties, Gene was the editor of the weekly newspaper. "I still remember the masthead," John says. "Under the name of the paper it said QUEEN CITY OF A GREAT DAIRY AND POULTRY EMPIRE."

Although Gene didn't have much formal schooling, the job suited him because he was inquisitive, literate, even literary. He read everything he could get his hands on. Once, he took a college extension course in Shakespeare at Tryon high school. (Years later, when John was in college, he met a professor who identified himself as the man who taught Shakespeare to Gene McIntyre.)

He was also a conservative Republican and so opinionated and firm in his beliefs that even when the Great Depression changed the family's status from poor to hand-to-mouth, he was appalled by the New Deal. "Dad disliked FDR down to the bottom of his feet," John says.

Once the Depression settled in, Gene couldn't keep a steady job. He sold cigars for a Guthrie tobacco company and later notions to country stores. For long stretches, he was unemployed. Lula somehow landed a job in town as assistant postmaster and this was the family's economic salvation.



The McIntyres had been married four years when, in 1943, he received both his commission in the U.S. Navy and his medical degree from the University of Oklahoma.

Both John and Ray can scarcely remember a time when they didn't work. John sold newspapers, picked cotton, mowed lawns. He recorded his revenue and expenditures in a ledger, which he still has. A typical entry:
PICKLE...5 CENTS.

Ray set up animal traps and sold the hides to people in the produce business. Opossum hides were worth a quarter, skunks fetched a dollar—a minor bonanza.

Although the economic gradations in Tryon were subtle and certainly not wide ranging, John and Ray agree that their family was at the lower end. But because nearly everybody in town was trying to survive the Depression, no stigma was attached to their poverty. The boys' development was normal and happy. John had many friends including one neighbor named Don Powers. Last year, Don came out of retirement to serve as the judge who is presiding over the multi-county grand jury investigating Governor Walters' 1990 campaign financing.

Like their father, the boys were avid readers. It was probably through books that John first realized the almost limitless possibilities outside of Tryon. The best ticket out seemed to be college, and though John had been the valedictorian of his class of sixteen in 1934, money was a daunting obstacle. Their parents always had dreamed about a college education for their sons, but there was no extra money. "They encouraged me to go, but I'd have to do it on my own," John recalls.

He also received encouragement and support from his high school principal, Hershel Jones. He had recognized John's potential early on, but even he was surprised when John announced that he wanted to become a doctor. "Mr. Jones and my parents thought medical school was unrealistic economically, but at least they didn't tell me I was crazy."

John can't remember when, why, or how he became attracted to the medical profession. It wasn't through contact with any physician. "I was never sick and was only injured once bad enough

to be seen by a doctor. On just about the first day of football practice, I hurt my knee. It was swollen and discolored and the doctor wanted to tap it."

John took a look at the syringe and exerted his right as a patient not to be treated. That day marked the end of his football career and his contact with doctors, at least for several years. Nevertheless, he resolved to go to medical school.

John left home with his life savings, $25, to attend Central State College in Edmond. The money would pay for tuition and books, but he decided not to enroll until he had found a job. After a couple of days without any luck or even any leads, John was about to return to Tryon when he again met the president's secretary, who handled job applications. When he found that John still didn't have a job and was about to leave, he told the dejected young man that he would give him a job for $10 a month.

That was a start. Room and board was $14 a month. After a month, the secretary gave John a higher paying job and the immediate threat of running out of money was over. John believes to this day that his high school principal Hershel Jones was probably responsible for getting him that job. As a good alum of Central State, Jones had strongly promoted his school to John.

John's new job was in the correspondence office. The office of the Dean of Women was across the hall, and John couldn't help but notice a part-time secretary named Catherine Defenbaugh, from Bartlesville. By their junior year, socializing had become steady dating, and they decided



before their graduation in 1938 to get married as soon as possible.

As much as he wanted to go to medical school then, John didn't have the money, and in fact had to pay off a loan to Central State. So he took a teaching job in Marlow, near Duncan. Catherine was teaching in Davenport, ironically in Lincoln County, but 130 miles from Marlow. They waited as long as they could to get married, until January 1939. They honeymooned for a weekend in the Biltmore Hotel in Oklahoma City and then returned to their respective communities.

In Davenport the rule was only one breadwinner per family. If the school officials had discovered that Catherine was married, she would have lost her job. So she didn't tell anyone who might tell until the end of the school year, and then she found a school board with a more liberal policy. They both taught another year, again in different towns, but at least their marriage didn't have to be secret.

"I liked teaching, the teacher-student contact," John says. "But the money was awful and I certainly didn't care for a teacher's



Dennis K. McIntyre, MD, stands with his father, John, in front of Enid's St. Mary's Hospital. It has been John's professional home for many years and achieved much of its growth during his tenure as chief of staff.

extracurricular activities, lunchroom duty, and so forth." So he applied to the University of Oklahoma medical school, and with his near straight-A college average there was little chance he wouldn't be accepted.

The class that started in 1940 had 57 members. One of the profs told them that 10 percent wouldn't make it. He was slightly off; seven had dropped out by the end of the semester. John McIntyre was not among them because for the first time in many years he wasn't also holding down a job and because he knew how to study. "I had one rule that was inviolable: I went to bed by midnight. Many of my classmates stayed up all night cramming, and I know they didn't learn a damn thing."

He did so well on the tests that first semester that he felt confident enough to take a job. It was in the anatomy lab, "taking care of the cadavers."

During his second year, with the U.S. hovering on the brink of World War II, McIntyre joined the navy, called the hospital volunteer probationary, "to get the draft board off my back. Then following Pearl Harbor, they made us all apprentice seamen, the lowest of the low. But we didn't mind because we started to get paid and go to school year-around."

McIntyre felt almost as confident with his patients during medical school as he did taking tests in basic science. "I remember my first third-year patient like it was yesterday," he says. "She was a colored lady with rheumatic heart disease and congestive heart failure. I'm sure she had been examined by numerous students, residents, and attendings, and there I was tentatively asking her to go through the whole routine again. And despite the pain and anxiety she must have been feeling, she was extremely patient with me. I learned a lot from her.

He was off to a good beginning in the art of medicine, and he was able to develop it further while simultaneously eschewing all overtures of performing surgery ("I didn't even like to assist.") during his nine-month internship at the navy hospital in Norman.

At one point, he played a small role in Oklahoma's medical history. He transported a vial of 10,000 units of penicillin from Norman to Oklahoma City to Harry Wilkins, Oklahoma's first neurosurgeon, who wanted (but otherwise couldn't obtain) the new antibiotic to treat a patient with a brain abscess. "It was Harry's first time to use penicillin," McIntyre says. "It worked beautifully and over the years he mentioned it every time we ran into one another."

McIntyre's war-accelerated class graduated in December 1943. Following his internship, he immediately joined 400 other young naval officers aboard a ship in San Francisco bound for New Guinea. "As we were docking," McIntyre says, "we heard Toyko Rose on the radio announcing that 400 young American officers had just arrived in New Guinea."

Welcome to the war.

* * *

As General MacArthur promised, he returned to the Philippines, and with him were thousands of American soldiers and sailors determined to rid the archipelago of its Japanese occupiers. John McIntyre's part in that effort was short but intense. Between Christmas and New Year's in 1944, he was on a ship that was part of a convoy headed from the Leyte Gulf to the island of Mindoro. The ships were under intermittent attack for about 24 hours, culminating when a Japanese pilot decided to give his all for the emperor and sail his plane down the smokestack of an ammunition ship.

"Like a damn fool, I was up on deck watching, and the ship that blew up was next to us," McIntyre says. "The next thing I knew, my arm was broken."

The explosion killed 16 and



The McIntyres admire a porcelain figurine they acquired during one of their several trips abroad.

wounded many others on board and the scene was pure pandemonium. Given his own injury, McIntyre did what he could for the other casualties, mainly "bossing around" those who could physically care for the wounded.

The explosion occurred at 10 AM. They sailed all day, with no further attack until dusk. "Right off, we took a torpedo in the engine room and started to sink," McIntyre says. "I was lucky. I got on a landing craft and never even got my feet wet."

But the rest of that night was "utterly terrifying. We were under constant attack, zigzagging through the Sulu Sea to Mindoro. For me that was a day and night of sheer hell. I was thinking, how could I stand going back out there for more. I didn't know if I could."

Fortunately, he didn't have to. He was hospitalized and then returned to the states for reassignment. For some confounding reason, Dr. McIntyre spent the rest of the war (and then some) recruiting stewards mates in Macon, Georgia. He wasn't very busy and the duty was boring, but Catherine had joined him. After VJ Day, gas rationing was lifted and he and Catherine took several car trips through the South. It was a perfect way to be reunited and was the debut of their many travels together over the next half century.

* * *

TO GET MORE HOSPITAL training, McIntyre in 1946 entered a mixed or general residency at a hospital in Cedar Rapids, Iowa. Two internists who were practicing excellent, state-of-the-art medicine enticed McIntyre toward an internal medicine residency. But the brutal Iowa winter and the desire to settle into a practice and community led to his decision to leave Cedar Rapids after nine months.

In hindsight, this decision not to pursue board certification has been McIntyre's one regret professionally. "In the present climate of practicing medicine, you ain't nothin' without it," he says, though agreeing that board certification would have only added a bit more prestige.

But if he regretted leaving the residency, he regards his next move as one of his best: setting up in Enid in 1947. "We didn't know anyone here, and I was apprehensive about starting a general practice without any patients," McIntyre says. "We had saved a little money and figured we could live on it a year if need be. But my attitude was the same as when I entered medical school: if I can't make it here, I'll have to go somewhere else."

Enid in 1947 had a general population of about 30,000 and a doctor population of about 30. "I didn't know any of them," McIntyre says, "but they seemed neutral toward me. One of them said, 'We'll fight you, but we'll fight you fair.'"

Initially, there were long stretches of sitting around reading journals. Then he started doing physicals on veterans for the Veterans Administration, and within six months, his office manager, Catherine, was able to report that the practice was in the black. He was making enough money to provide small loans to his brother Ray, who that same year had entered the O.U. medical school.

As a budding organization man, John joined the Kiwanis Club, county medical society, state medical association, and Presbyterian church and devoted time to each. He and Catherine were happy in every way but one. For several years, they had been trying to have children and for no explicable reason, they had been unsuccessful. Perhaps they just needed a new decade. Dennis was born in 1951, and Mary less than a year later.

By that time, Ray, had become a physician and was practicing in nearby Kingfisher; and John had two partners, Drs. Evans Talley and B.J. Cordonnier. "The deal was, I'd do the internal medicine, and they'd do the surgery," McIntyre says. "The only exception to that was I did a lot of tonsillectomies for the county welfare organization. I had more time than the older established doctors."

During Ray's first year in Kingfisher, he filled otherwise idle time by making rounds with his brother at St. Mary's hospital. "John was very skillful at extracting useful information from the patient while being kind and compassionate. Observing him in those settings, I'd often say to myself, 'So that's how you do it.'"

During the fifties, he adjusted his practice by quitting OB. "In a way, delivering babies is wonderful because it is so rewarding and everybody is happy," McIntyre says. "But it got so I hated to go to bed at night because I KNEW I was gonna have to get up. And OB is so time-consuming that you ironically wind up tending to neglect your own family."

About the same time, he also stopped being a preceptor for the medical school. "I had some good preceptees, no question about it; people like Tom Lynn (who became dean of the medical school) and Dick Marshall (director of medical education at Tulsa's St. Francis Hospital). But after about three bad ones, sloppy and undependable, I opted out. Three months can be an awful long time when you're stuck with someone who probably shouldn't even be in medicine."

Throughout the fifties, whenever the McIntyre brothers got together they enjoyed talking over the clinical aspects of their practices. But by the sixties, their conversations likely as not involved the political and socio-economic aspects of medicine.

"When Medicare was passed, I had considerable dread about the future of medicine," Ray says. "I don't think John was nearly as worried as I was; things would somehow work out. Maybe I looked at it like the enlisted man I was in the army. We were always told what to do, and every time there was a screw-up, we caught the brunt of it. John, you know, was an officer."

While John admits that his brother was more upset, he says he was distressed by Medicare because it was clear that doctors' authority would decrease and



John McIntyre and Rod Frates, president of C.L. Frates & Company, discuss PLICO business.

government's authority would increase. However, it was pure coincidence that when Medicare passed in 1965, John became a member of OSMA's Board of Trustees. He was appointed to fill an unexpired term.

By the end of that term, he felt an even greater need to continue in a leadership position. "By then, my son, Dennis, was showing a lot of interest in medicine; he was even going on rounds with me. And I felt that this government encroachment would affect him far more than me."

McIntyre served two more full terms on the board and was chairman from 1974 to 1976. About the same time, he helped devise and implement Oklahoma's pilot utilization review program. "We saved some money (more than $13 million during a period in 1977, compared to the same period in 1976) and identified some physicians who needed help."

Although the project had been successful, McIntyre believes the die had already been cast by the government. Gradually, government-sponsored physician review, he says, has switched its emphasis from educating physicians to punishing them and saving money. "This happened during the five years I served on the PRO board and was its president. The PRO today still says they are educating physicians. But I know that's not true from first-hand experience. Few have been more hassled by the PRO than me. Their education comes in the form of a one-page letter saying that a reviewer says so and so. Why is the reviewer's opinion better than mine? There is no appeal. I know. I've written a jillion letters, and none of them have done a damn bit of good."

Sounds pretty downbeat. With no trace of smugness, Ray says that John has become very disenchanted with the government's increasing meddling over the years. This has been particularly true since John served as OSMA president in 1982 and 1983. "Things seem to have escalated downward since then—not that I had anything to do with stemming the tide.

"The worst thing I faced was the failure of Penn Square Bank. As a result, OSMA lost several hundred thousand dollars, but we did eventually recover about 65 percent of the loss."

* * *

IN HIS 77TH YEAR, JOHN McIntyre still sees patients in his first floor office of the professional building across the street from St. Mary's. In his first years in Enid, St. Mary's was a snug, red brick building. Since then, two large wings that dwarf the original have been built, the north one while John was chief of staff.

Why would this man who admits his unhappiness at being hassled by the PRO and believes that even more government intervention in medicine is on the way, still be practicing? There are at least two reasons.

One is probably his experience in helping to create and direct OSMA's highly successful malpractice insurance company, PLICO, the Physicians' Liability Insurance Company. In the seventies, many insurance companies began dropping physician malpractice insurance following a number of large court settlements and a tremendous increase in the number of claims filed. Although much of this litigation had occurred in California, lawyers nationwide were quick to emulate the success of their West Coast brethren. As a result, the rates paid by physicians in Oklahoma—where claims didn't increase much—rose by more than 200 percent from 1974 to 1979.



When John was named Private Practice Physician of the Year, Dr. and Mrs. Ray McIntyre, Dr. and Mrs. John McIntyre, and Dr. Dennis McIntyre were present.



"His practice has been the centerpiece of his intellectual life," says John's brother, Ray.

Twice during the seventies, the OSMA Council on Member Services asked Rod Frates of C.L. Frates and Company to find companies large enough and willing to provide malpractice insurance coverage to the membership. Among the leaders of this council were McIntyre and the late Dr. C. Alton Brown of Oklahoma City.

Frates succeeded both times, but by the late seventies, no one was satisfied with the rising premiums and with the virtual certainty that premiums would continue to soar in an incredibly shrinking market of carriers. Brown and McIntyre asked Frates to explore how OSMA could form its own insurance company.

When Frates's report showed the financial and coverage advantages of OSMA forming its own company—and when the current commercial carrier's malpractice insurance rates increased 32 percent from 1978 to 1979—the trustees voted unanimously to develop PLICO in 1980.

The details of PLICO's formation are contained in a JOURNAL feature story that ran in the March 1988 issue. The point is that, according to Frates, OSMA members have saved more than $300 million in premiums since 1979. PLICO is also the only malpractice insurance company in the U.S. that offers occurrence coverage, including any event which occurs during the policy year regardless of when the lawsuit is filed.

As a PLICO trustee since its inception and a former chairman of the claims committee, John McIntyre has played a major role in the company's success. Today, as president and chairman of the board, he is even more important to PLICO. Recently, when McIntyre recognized that the federal government would likely require more reserves in the near future, he persuaded the House of Delegates to call a special meeting to vote to infuse additional capital into the company.

His recommendation was accepted almost without question, says Rod Frates. "It was a wise anticipatory move," he says. "And not everyone could have pulled it off. Those house members are all very bright people, but they trust John and rightfully so. They know he's honest and has good judgment. A different person in his position might have had trouble persuading the delegates to vote his way."

The second reason McIntyre would still be seeing his patients is probably even more pertinent. When his younger brother Ray announced his retirement last year, John told him he would probably never quit. "Since then," Ray says, "he's told me: 'Maybe I better think about how to quit.'

But I don't think he's gonna retire any time soon.

"Emotionally, the guy doesn't have anything to replace his practice. He likes to play golf and travel with his wife, but his practice has been the centerpiece of his intellectual life. He's worked like hell to become a superb clinician, and I think he's better now than ever."

When his son, Dennis, established his internal medicine practice in Enid a few years ago, "everybody thought I was going to quit then," John says. "But that was the farthest thing from my mind. And I still have no wish to retire. My life is more trouble-free than it's ever been. I don't have as many patients as I used to, but that's good, too. With Dennis covering for me, I can do anything I want. And I think the quality of my practice is as good, and maybe even better than ever. My health is good, knock on wood.

"Why in the world would I quit a setup like this? It's what you strive for... it's ideal."

Begun in 1981, the Leaders in Medicine series honors some of Oklahoma's most outstanding physicians. This the twenty-fourth article in that series.

Richard Green is a freelancer who has been writing the Leaders stories for a number of years. Robert Taylor is a freelance photographer. Both are based in Oklahoma City.



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AMA Hospital Medical Staff Section meets June 10-13 in Chicago

The Twenty-First Annual Meeting of the AMA-HMSS in Chicago June 10-13, was attended by the following representatives from the Oklahoma State Medical Association Hospital Medical Staff Section. Representatives attending were William O. Coleman, MD, Clarence Robison, MD, and Michael Schwartz, MD, Oklahoma City; and Norman Sneed, MD, Checotah.

There were three informational sessions: the first was "Negotiations and Conflict Resolution; the second, "A Review and Analysis of President Clinton's Health Care Reform Plan"; and the third, "Challenge and Change in the Managed Care Environment."

The AMA-HMSS considered 63 resolutions and 14 HMSS Governing Council Reports. Fifteen resolutions were forwarded to the AMA House of Delegates and two resolutions were referred to the Board of Trustees.

Economic credentialing, managed care, hospital exclusive contracting, and hospital purchasing of practices were the subjects of some of the resolutions. The AMA House of Delegates adopted a resolution asking that the AMA Board of Trustees study the sale of physicians' practices under all current situations, particularly those addressed by the Office of the Inspector General of Health and Human Services and the Internal Revenue Service, and report back to the House of Delegates at the 1993 Interim Meeting.

The concept of enterprise liability was strongly opposed in both the AMA-HMSS and the AMA House of Delegates. The AMA affirmed its position that effective medical liability reform based on California's MICRA model is integral to health system reform, and must be included in any comprehensive health system reform proposal that hopes to be effective in containing costs, providing access to health care services, and promoting the quality and safety of health care services.

The AMA-HMSS was created in June 1983 and has proven to be an excellent method for physicians to access the AMA and the AMA House of Delegates, and to be an integral part of the policy-making process.

—William O. Coleman, MD
Chair, OSMA-HMSS

New state association presidents introduced to AMA House of Delegates



OSMA President Lance Miller, MD, takes his place on stage as the 1993-94 president from each state association is introduced to the AMA House.



From her vantage point on the floor of the AMA House, Judy Miller (c) watches proudly as her husband is introduced.

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Oklahoma delegation kept busy at the AMA meeting in Chicago



Oklahoma delegates Perry A. Lambird, MD, Norman L. Dunitz, MD, and Joe Crosthwait, MD, follow the AMA house proceedings. At the table behind them (from right) are Michael J. Haugh,



MD, John R. Alexander, MD, and Boyd O. Whitlock, MD. (Right) Also seated as members of the Oklahoma delegation are Ronald O. Coleman, MD, and Gary F. Strebel, MD.

Rural health association releases papers on relevant health issues

The National Rural Health Association (NRHA) recently released three new working papers on tort reform, capital funding for health facilities, and graduate medical education reform. The papers explore how these areas can be reworked to improve health care in rural areas and are entitled "Rural Health Tort Reform," "Access to Capital Funding for Rural Health Care Facilities," and "Graduate Medical Education Reform to Increase Providers in Rural Areas."

Rural Health Tort Reform. The NRHA Task Force on Tort Reform concluded that the current medical malpractice environment poses a nationwide threat. The task force specifically examined three tort reform policy statements of the American Academy of Family Physicians, the National Advisory Committee on Rural Health, and the National Medical Liability Reform Coalition. While all of these policies would improve the malpractice climate, the NRHA says they do not adequately address those areas that are specifically problematic for rural areas—particularly obstetric services that have been decimated in rural areas due to high malpractice premiums resulting from the greater likelihood of rural physicians being sued. This paper discusses the task force's findings and presents recommendations for improving tort reform with respect to rural health care needs.

Access to Capital Funding for Rural Health Care Facilities. Access to capital funding is critical to viable rural health systems and in the expansion of rural infrastructure. This paper examines past federal capital funding efforts and the current lack of capital funding for rural facilities. A recent Office of Technology Assessment study found that many rural hospitals are using their cash reserves to maintain current operations and therefore have fewer resources available to help fund capital improvement projects. It becomes more difficult to attract rural providers when urban centers can offer the latest technology and modern facilities. The paper discusses past funding projects and makes recommendations for future efforts to facilitate capital funding for rural health care facilities.

Graduate Medical Education Reform to Increase Providers in Rural Areas. This working paper examines ways to reform graduate medical education to better meet the needs of rural and medically underserved populations. It expands and updates an earlier nrha working paper, "The Role and Responsibility of America's Colleges of Medicine in Addressing Rural Health" (included as an appendix). The paper calls for graduate medical educators to promote service in medically underserved and rural areas as a career worthy of the best students, and to develop curricula that expose medical students to these practice options. The paper is divided into three areas; a set of assumptions, eight necessary components that graduate medical education reform proposals must address, and four strategies for implementing such reform.

Copies of the three NRHA papers may be obtained for $5 each from the NRHA, 301 E. Armour Blvd., Suite 420, Kansas City, Mo. 64111. Orders totaling less than $50 must be prepaid, or they may be charged to Visa or MasterCard.

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Bill designates University Hospitals as agency separate from DHS

The Oklahoma Medical Center officially became The University Hospitals on July 1, in accordance with Senate Bill 423.

The bill separated the hospitals from the Department of Human Services, making them an independent state agency. Under the provisions of the bill, Oklahoma Memorial Hospital has changed its name to University, while Children's Hospital of Oklahoma, the O'Donoghue Rehabilitation Institute, and MediFlight Oklahoma will retain their names.

Dr. Andrew A. Lasser, chief executive officer of the University Hospitals, stressed that they will be a separate state agency providing medical facilities to the University of Oklahoma and other higher education institutions throughout the state. He explained that the hospitals will operate under a new governing authority, the University Hospital Authority.

The name University Hospitals is not an indication of ownership, Dr. Laser noted, but instead explains their role, location, and major affiliations.

Dr. Lasser complimented the Department of Human Services for providing 20 years of leadership for Children's Hospital and 13 years for the rest of the hospital complex.

"But DHS is a huge agency," he said. "One of the advantages (under the new bill) is that this new authority gives us a board of directors that has the hospitals as its only focus."



Mark Royal Johnson, MD
1923 - 1993

Editor-in-Chief, OSMA Journal, 1968-89
Editor Emeritus, 1989-93

The physician ought to know literature, to be able to understand or to explain what he reads. Likewise also rhetoric, that he may delineate in true arguments the things which he discusses; dialectic also so that he may study the causes and cures of infirmities in the light of reason.

—St. Isidore of Seville
Etymologiae, IV

HEALTH DEPARTMENT

Rapid AIDS test still controversial

The federal Food and Drug Administration licensed a 10-minute diagnostic test kit to be used by health professionals to test for the presence of HIV-1 some time ago, but the subject is still a topic of controversy.

The screening test is licensed as only a screening, not diagnostic test. It has a limited distribution similar to the distribution of HIV-1 EIA. It was marketed for small offices, clinics, emergency rooms, etc. where traditional HIV testing may be impractical or unavailable. Due to CLIA regulations the test is only supposed to be used within a laboratory setting. However, there is the potential for underground distribution of this test kit.

The new 10-minute diagnostic test is very sensitive (99.9%) and specific (99.6%). However, these figures were derived under ideal circumstances in the laboratory; the test may be quite a bit less accurate when used in non-laboratory settings. And given the low prevalence of HIV-1 in our population, many of the positive test results will be false positives. Therefore, any person who has a reactive rapid test should be told there

In Memoriam

1992

Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28

1993

Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd Bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
William Niebuhr Weaver, MD	March 20
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Chester Randall Seba, MD	April 4
Edward Cotter Murray, MD	April 9
Eric McLain White, MD	April 23
John Franklin DeJarnette, Jr., MD	May 1
Harold Alwin Smith, MD	May 4
Kenneth Warren Bonham, MD	May 28
John Raymond Stacy, MD	July 6
Carl Davis Osborn, MD	July 11
Mark Royal Johnson, MD	July 12
W. Turner Bynum, MD	July 13

Rapid AIDS test *(continued)*

is a need to have serum sent in for an EIA and Western blot for confirmation. The Oklahoma State Board of Health now requires that a positive HIV screening test must be confirmed with an HIV-confirmatory test prior to reporting a positive result. Any laboratory failing to do so will have its license revoked.

The controversy surrounding the HIV-1 rapid AIDS test stems from the dilemma of its use. If the test results are negative and the patient is aware of the six-month window, there is no apparent problem with the 10-minute test. However, because of the great possibility of a false positive, physicians would be responsible for counseling every patient about the likelihood and meaning of a positive screening. How would a physician prepare a patient for a false positive? Patients may experience unnecessary stress and anxiety if the results they are expecting in 10 minutes are delayed or if another test is required.

As an example of the accuracy of the test, consider its use in two Oklahoma populations for which seroprevalence data are available. The HIV-1 seroprevalence among black male applicants to the armed forces in Oklahoma City is .49%, or 1 in 200. In persons from this population, 56% of the positive test results would indicate a true infection (positive predictive value) so that 44% of the positives would be false positives. In a lower risk group such as the statewide population of women of childbearing age at delivery, the HIV-1 seroprevalence is .04%, or 1 in 2,500. In persons from this group, only 9% of the positive test results would reflect true infections; 91% would be false positives. Obviously there is much potential for anxiety because of false positive test results. On the other hand, because of the high test specificity and the low HIV-1 prevalence, a negative test result is 99.99% reliable. Although the six-month caveat must be observed, persons with a negative test result using this new diagnostic kit can certainly be considered to be free of HIV antibodies at the time of the test.

The value of this test must be measured by individual physicians. The benefits of a quick result measured against the possibility of a false positive and the stress and anxiety placed upon the patient thereafter will determine the magnitude of this scientific advance.

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Deaths

Kenneth Warren Bonham, MD
1903 - 1993

Retired general practitioner Keith W. Bonham, MD, died May 28, 1993, in Enid. A native of Leesville, La., Dr. Bonham attended school in Louisiana and east Texas before earning his medical degree at the University of Texas Medical Branch in Galveston in 1930. Service as a medical missionary kept him in India during many of his professional years. In 1968, he moved to Enid, where he served as a physician at Phillips University Clinic. In 1973 he was granted Life Membership in the OSMA.

W. Turner Bynum, MD
1910 - 1993

OSMA Life Member W. Turner Bynum, MD, died July 13, 1993, in Oklahoma City. A native of Oklahoma City, Dr. Bynum attended the University of Oklahoma School of Medicine, earning a B.S. in medicine in 1932. He was graduated from Northwestern University in Chicago with an M.B. in 1934 and an M.D. in 1935. His internship was served in Oklahoma City, where he opened his first office for the practice of internal medicine. He had moved to Chickasha by the time he entered military service in 1943, serving with the U.S. Marine Corps in the Pacific. In 1947, he returned to Oklahoma City, where he practiced until his retirement in 1988. He also served on the faculty at the OU School of Medicine, from which he was a retired emeritus clinical professor of internal medicine.

Mark Royal Johnson, MD
1923 - 1993

Mark R. Johnson, MD, a 1946 graduate of the University of Oklahoma School of Medicine, died July 12 at his home in Oklahoma City. He served with the U.S. Air Force in the Azores during World War II, and later with the Army's 45th Division in Korea. In addition to a private practice in internal medicine, begun in Oklahoma City in 1954, Dr. Johnson was active in a number of other professional activities including two terms as secretary-treasurer of the OSMA (1956-62); membership on the University of Oklahoma Board of Regents (1960-67); editor-in-chief of the OSMA JOURNAL (1968-89) and editor emeritus (1989-); professor of medicine at his alma mater (1979-82); secretary of the Oklahoma State Board of Medical Examiners (1982-88); and medical director of the Rehabilitation Institute of Oklahoma (1982-88). After his 1992 retirement from private practice, he became medical director of Aetna Medicare for Oklahoma. He also volunteered his services at the Little Flower Clinic in Oklahoma City. Dr. Johnson was featured in the JOURNAL's Leaders in Medicine series in January 1993 and was also honored with an anthology of his editorials in the June 1989 issue. Memorials may be directed to the Mark R. Johnson Memorial, c/o Executive Director, Oklahoma State Medical Association, 601 Northwest Expressway, Oklahoma City, OK 73118.

Carl Davis Osborn, MD
1921 - 1993

Ada gynecologist Carl D. Osborn, MD, died July 11, 1993. Dr. Osborn was born in Strang, Okla., and earned his medical degree from Southwestern Medical College (now University of Texas Southwestern Medical School) in Dallas in 1945. He completed his internship at Hillcrest Memorial Hospital in Tulsa and became an associate staff of Ada's Valley View Hospital.

John Raymond Stacy, MD
1914 - 1993

OSMA Life Member J. Raymond Stacy, Oklahoma City, a retired orthopedics specialist, died July 6, 1993. Dr. Stacy was born in Coeur d'Alene, Idaho, earned his B.A. degree from Oberlin College in 1937, and medical degree from Case Western Reserve Medical School in 1942. During World War II he was a first lieutenant in the U.S. Army Reserve. Dr. Stacy practiced orthopedic surgery in Oklahoma City for 38 years and was a clinical professor at the University of Oklahoma School of Medicine. He was a past president of the Oklahoma Orthopaedic Society.

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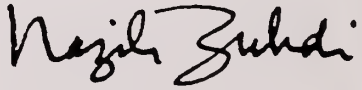
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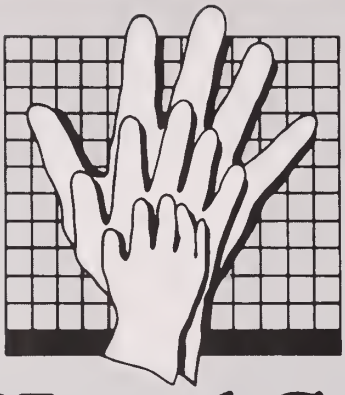
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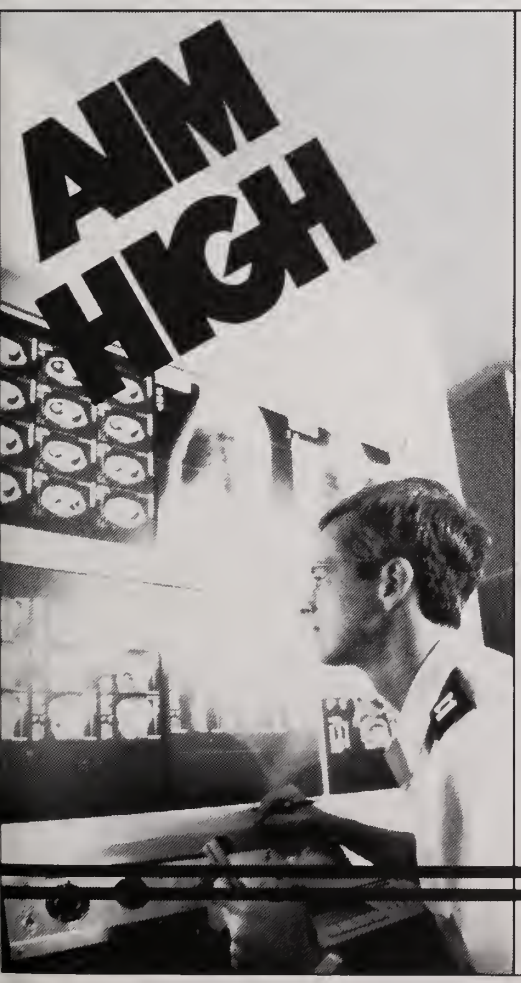
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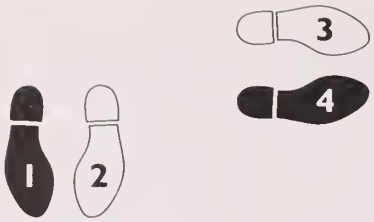


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The Last Word

■ **Ways to reduce patient injury and malpractice** claims resulting from medication errors were among the major findings of a study released during the 1993 annual meeting of the Physician Insurers Association of America (PIAA). Errors related to the prescription of medication are the second most frequent and second most expensive procedure in claims against physicians, according to the PIAA. The study indicated that the four most common errors triggering malpractice lawsuits related to medication errors are incorrect or inappropriate dosage, medication inappropriate for a patient's medical condition, failure to monitor for drug side effects, and communication failure between physician and patient. Copies of the complete study are available from Tony Sullivan, Medit Communications, (708) 665-7510.

■ **The Tulsa County Medical Society recently released** the following position statement on practice parameters: (1) Tulsa County Medical Society endorses the concept of the utilization of Practice Parameters to maintain and further promote the quality of medical care and to contain health care costs. (2) Tulsa County Medical Society shall act as a facilitator by providing current clinical resource and reference on specific Practice Parameters for use by hospital medical staffs in the development and sharing of their Practice Parameters. (3) To facilitate the adoption and utilization of Practice Parameters by local hospital clinical departments and medical staffs, TCMS will provide forums for physician representatives appointed by their respective hospitals. The forums will provide discussion of specific nationally developed Practice Parameters.

■ **More than 400 letters demanding tort reform** have been sent to Hillary Rodham Clinton as a result of an AMA-sponsored campaign. In June the association launched a campaign that included asking physicians to write letters. The campaign was created to ensure tort reform is included in President Clinton's system reform plan [Mrs. Clinton's remarks on tort reform to the AMA House of Delegates appear elsewhere in this issue.] Many physician wrote they are paralyzed by frivolous malpractice actions and unconscionably high premiums. Copies of the letters, which also were sent to the AMA's Washington office, will be shared with key Washington leaders.

■ **The annual OSMA-sponsored picnic for freshman** OU medical students and their families will be held Friday, August 20, at the Oklahoma City Zoo's Aquaticus facility. Running from 5:30 to 7:30 P.M., the event will feature an Aquaticus show and ample supplies of typical picnic fare. The picnic has been a popular event for a number of years, allowing new students to get to know one another, learn a bit about organized medicine, and have one last fling before settling into their study routines. Last year's picnic, the first held at Aquaticus, was particularly successful, with everyone enjoying the picturesque setting, shaded seating, cool breezes—and of course, the dolphins. Dress is casual. If you need additional information, call 843-9571.

■ **Dr. Ronald A. Greenfield's "Symposium on Antimicrobial Therapy,"** which has been appearing monthly in the JOURNAL since October 1992, has attracted the attention of the Southern Medical Association. SMA is now preparing the manuscripts for publication as a series of three or four booklets in its Clinical Concepts series. The papers may also become a part of the DialAccess system. The JOURNAL's editorial board honored Dr. Greenfield's work with its Charlotte S. Leebron Award earlier this year and is pleased to see him receive this additional, richly deserved recognition.

■ **The Oklahoma City Clinic, largest private** multispecialty medical group practice in the state, has entered into a longterm agreement with Caremark International, Inc., to manage its business operations. Under the agreement, Caremark will provide administration of patient services with respect to facilities, financial and information management, marketing assistance, and other business functions. Caremark has also acquired certain assets of the clinic, which has more than 100 physicians and some 550 non-physician employees at seven locations throughout metro Oklahoma City and western Oklahoma.

■ **Tulsa physician John M. Shane, MD, has published** a *CIBA Clinical Symposia: Evaluation and Treatment of Infertility* (Vol. 45, No. 2) that will be distributed globally. Dr. Shane specializes in reproductive endocrinology, infertility, and gynecology. ▯

ference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-ponse study. *Clin Cardiol.* 1991;14:146-151.

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NTRAINDICATIONS

ersensitivity to any component of this medication.

ctive liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

regnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during gnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cho-erol and other products of cholesterol biosynthesis are essential components for fetal development (including thesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis l possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal m when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated ing pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing only when such patients are highly unlikely to conceive and have been informed of the potential erds.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the ent apprised of the potential hazard to the fetus.

RNINGS

r Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than nes the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported 3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities not associated with cholestasis and did not appear to be related to treatment duration. In those patients in m these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the saminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic ough worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in patients.

s with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. m aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks he first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., out six-month intervals). Special attention should be given to patients who develop increased transaminase s. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more ent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinua-of therapy may warrant consideration of liver biopsy.

ctive liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see ITRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such nts should be closely monitored, started at the lower end of the recommended dosing range, and titrated to lesired therapeutic effect.

etal Muscle: Rhebdomyolysis with renel dysfunction secondary to myoglobinuria has been re-ed with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in statin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weak-in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit rmal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy ld be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked tion of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weak-particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if mark-elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should be temporarily withheld in any patient experiencing an acute or serious condition predisposing to development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major sur-; traume; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

e risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gem-il, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin her with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with statin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to uloskeletal symptoms in the group receiving combined treatment as compared with the groups receiving bo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated en of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment ued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use vestatin and fibrates should generally be avoided.**

CAUTIONS

ral: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

mozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homo-ys familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase hors are less effective because the patients lack functional LDL receptors.

al Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees al impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of astatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and e (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the e administered, and the degree of individual variability, patients with renal impairment who are receiving astatin should be closely monitored.

nation for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or ness, particularly if accompanied by malaise or fever.

n Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARN-G: Skeletal Muscle.

Cytochrome: Clearance by the cytochrome P450 system was unaltered by concomitant administration of prav-tin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that gnificant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cyto-e P450 system will occur.

Colestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after choles-ne or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bio-ility or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, ilability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not e plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been d with another drug in this class. Patients receiving warfarin-type anticoagulants should have their pro-bin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The AUC_{0-12hr} for pravastatin when given with cimetidine was not significantly different from the for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin iven with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but rall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin mfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, as a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination with pravastatin and gemfibrozil is generally not recommended.

eraction studies with *aspirin*, antacids [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine*, *digoxin*, *probucol*, or *probucol*, no statistically significant differences in bioavailability were seen when PRAVACHOL ministered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added tics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, glycerin.

rine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating erol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of tin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human ic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of oA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of . The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated ately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower erol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cim-that may diminish the levels or activity of steroid hormones.

xicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Hardenan gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurum* or *Eschenchia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitounnary				
Urinary Abnormality	2.4	2.9	0.7	1 2
Respiratory				
Common Cold	7 0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, penpheral neuropathy, peripheral nerve palsy

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia

Laboratory Test Abnormelities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interections.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

THE PRAVACHOL® DIRECTION IN LIPID MANAGEMENT

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- Excellent safety profile
- Easy for patients — once-daily dosing, well tolerated
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PRAVACHOL pravastatin sodium 20 mg tablets

PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

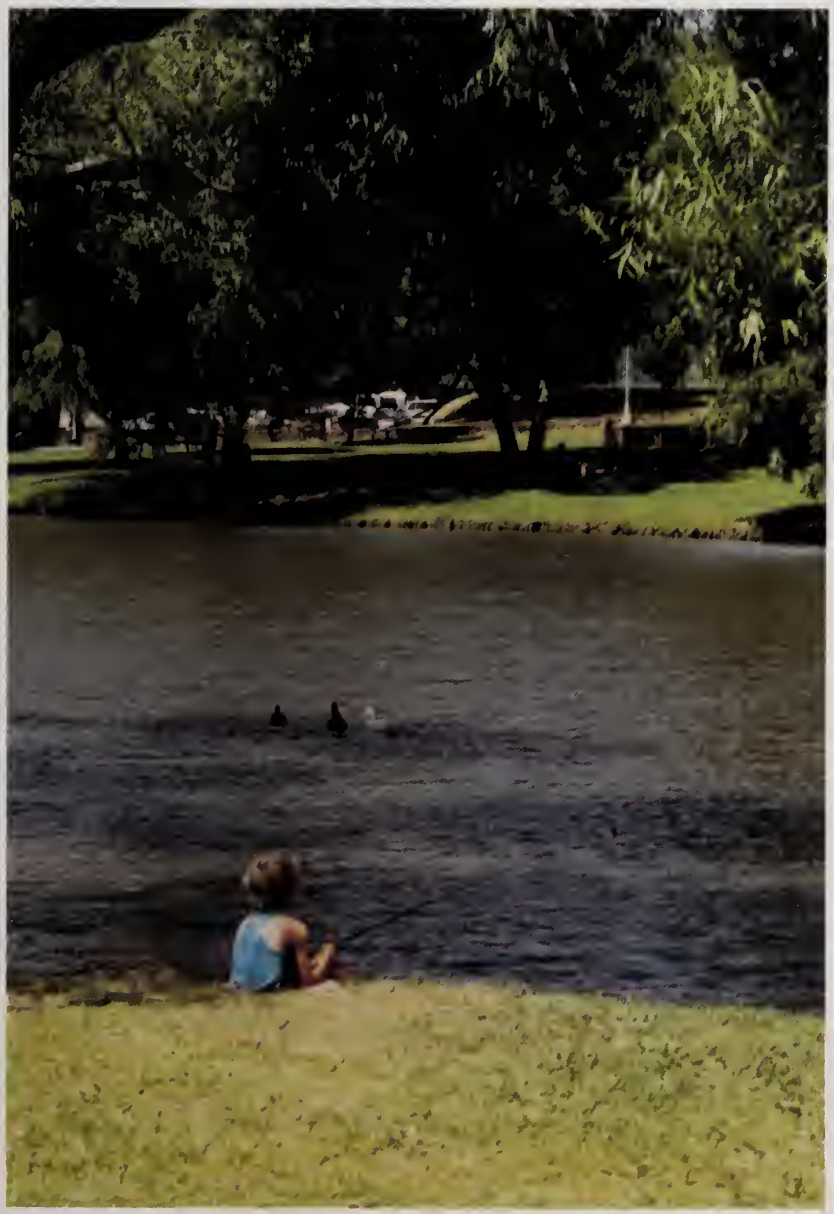
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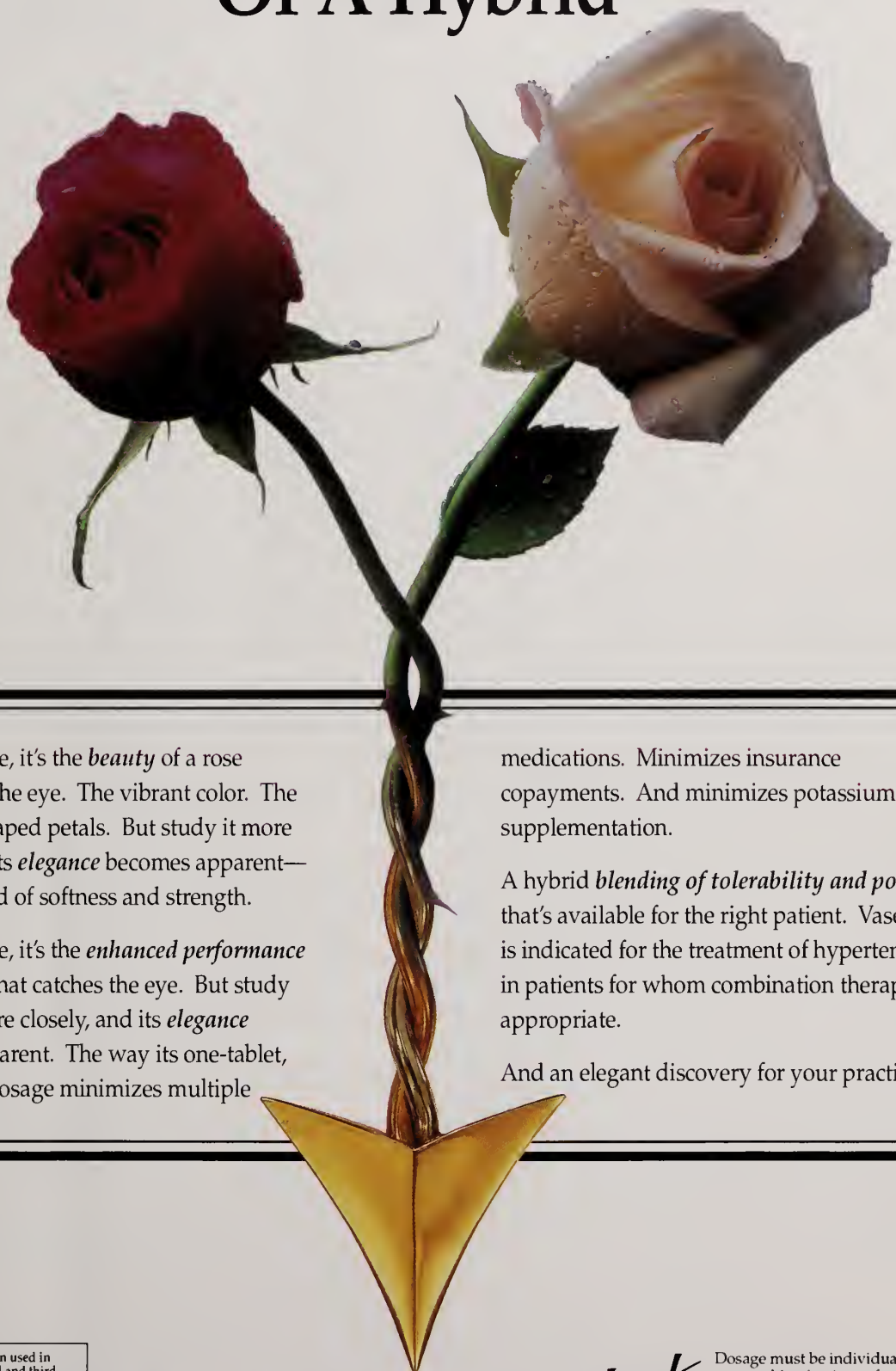
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Discover The Elegance Of A Hybrid



At first glance, it's the ***beauty*** of a rose that catches the eye. The vibrant color. The delicately shaped petals. But study it more closely, and its ***elegance*** becomes apparent—a gentle blend of softness and strength.

At first glance, it's the ***enhanced performance*** of Vaseretic that catches the eye. But study Vaseretic more closely, and its ***elegance*** becomes apparent. The way its one-tablet, once-a-day dosage minimizes multiple medications. Minimizes insurance copayments. And minimizes potassium supplementation.

A hybrid ***blending of tolerability and power*** that's available for the right patient. Vaseretic is indicated for the treatment of hypertension in patients for whom combination therapy is appropriate.

And an elegant discovery for your practice.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

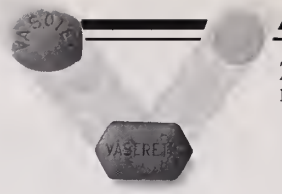
VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)



USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General; Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions,* and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide).*

Pregnancy; Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapril-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapril-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality,* below.)

Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC® should be discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function. Enalapril, which crosses the placenta, has been removed from neonatal circulation by peritoneal dialysis with some clinical benefit, and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5.6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspring. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects: These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate; Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapril and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent pre-existing renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapril has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.)*

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium).*

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglyceride levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions; Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with beta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapril and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapril is administered concomitantly with lithium.

Hydrochlorothiazide; When administered concurrently the following drugs may interact with thiazide diuretics:

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Cholestyramine and colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract by up to 85 and 43 percent, respectively. Thiazides may be administered two to four hours before the resin when the two drugs are used concomitantly.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possible decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic, and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* mouse

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*; sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings, Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest; myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction; pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia; atrial fibrillation; hypotension; angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression, a few cases of hemolysis in patients with G-6-PD deficiency have been reported in which a causal relationship to enalapril cannot be excluded; *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—Body as a Whole: Weakness; *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia; *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness; *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

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Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

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Indications: Yocon® is indicated as a sympathicolytic and mydriatic. It may have activity as an aphrodisiac.

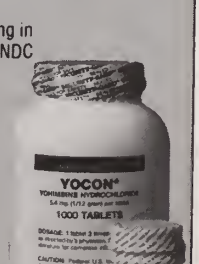
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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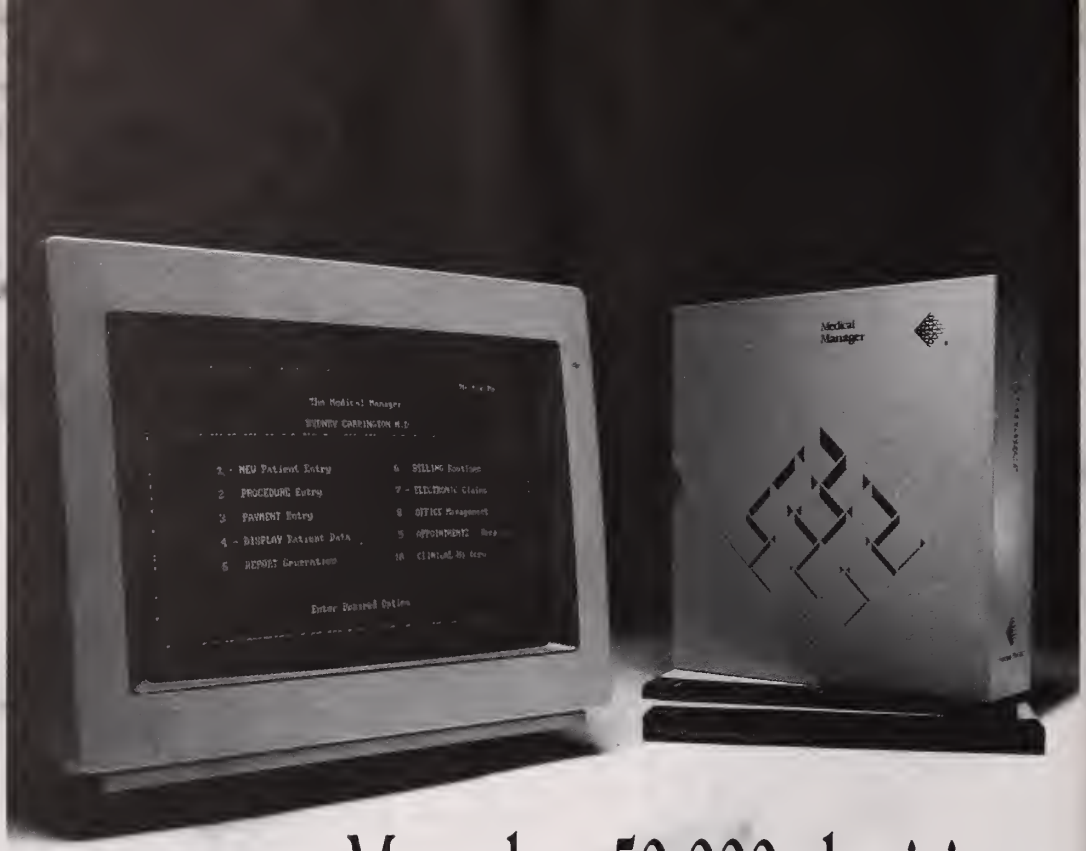
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Ray V. McIntyre, MD

Who Does This Patient Belong To?

In April, the OSMA House of Delegates passed a resolution warning of a threat of financial conditions attached to hospital staff privileges. The House re-emphasized the role of quality medical care in hospital staff appointments.

Physicians are alarmed that some hospitals require staff members to produce patient volume or patient billing quotas. The increased costs of technological advances and complex government regulations jeopardize many hospitals' financial health and leads to an increased use of entrepreneurial methods to increase cash income. But the departure from quality medical practice as the critical criterion for staff privileges is an alarming trend and calls for reassessment of the stipulations of hospital medical staff membership.

Modern hospitals are now the principal site where complex medical care is made available to the seriously ill and injured. The unwritten social compact between our people and the institutional hospital requires that all patients needing complex care be treated somewhere. But the complexity of scientific advances and government rules have made medical care so costly that facilities are provided only by very large capital investments. Concurrently, the correct use of the technical facilities requires the expertise of the professional physician, and thus a co-dependency of patient, physician, and hospital is put in place.

This hospital/physician/patient co-dependency is a source of considerable tension and probably induces some of the hospitals to try to attach financial conditions to medical staff privileges. Some hospitals avoid this controversy by hiring physicians to operate the hospital-owned facilities, but this leads to frequent ethical quandaries for the employed physician, who is then on the spot to juggle the patient's best medical interests versus the hospital's financial desires.

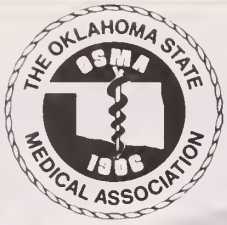
Every physician is free to be employed by a hospital, if willing to struggle with the ethical dilemmas. However, the licensed physician who is unwilling to accept hospital employment does not have a "right" to hospital staff privileges. The qualifications for hospital staff privileges partially coincide with those of medical licensure, but hospitals also need an ability to co-operate in the use of community resources, a spirit of collegiality in the hospital staff work, and a capacity to accommodate to peer review and cost problems.

Physicians as a group are often characterized as "poor business managers" by financial experts. The overgeneralization obscures, in some circles, the fact that most physicians *do* have a unique insight into the health care *effects* of economic phenomena that financiers rarely have.

So there is a complex ballet dance of disparate forces and interests that must be integrated to deliver modern medical care, and the divergent interests of those several parties must be restrained for a successful outcome. The one lode star that must always guide all the individual players is the best medical care of the patient if the longterm best interests of society are to be realized.

After all, the patients belong to themselves, and we all are their servants.

Ray V. McIntyre, M.D.



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G. Lance Miller, MD

Clinton's Tulsa Disclosures



On August 16, I had the privilege of representing this association at the National Governors' Conference in Tulsa and of hearing the President's initial unveiling of his long-awaited health care reform package. It was not expected that the President would unveil the details of his plan on this date and such was the case.

As expected, the Clinton plan will provide a federally mandated health care system framework to assure cost containment and universal access by allowing each state to design a plan unique to its own needs which meets the basic requirements of the federal guidelines. Mr. Clinton emphasized a strong role he expected each state to play in designing its own health care system. In anticipation of this approach, the OSMA has been dutifully working on an Oklahoma health care reform plan for several months.

The following are elements of the national plan which were revealed by President Clinton on August 16th:

1. Universal, simplified paperwork
2. Security—An individual cannot be denied insurance coverage because of pre-existing medical conditions, or loss or change of job.
3. Maintainance of private sector control by a managed care mechanism
4. Budget—Mr. Clinton did not use the term *global budget* and did not fully explain this element
5. Insurance reform—Community rating and risk pooling mechanisms for small businesses are the only explanation for this element
6. Significant increase in research and technology
7. Folding of the medical part of workers' compensation into the health care system
8. 100% tax deductibility for self-employed individuals

Expanding on the universal coverage element of his plan, President Clinton stated that he had ruled out the single-payor system and individual mandate (basically the Heritage Plan approach). Mr. Clinton stated that his plan would build on our current system using employer mandates with a long phase-in and limits of coverage for lower income individuals.

It was heartening to hear the President state that no one would have a free ride under his system. He emphasized a need for shared responsibility for everyone—employer and employee. Not discussed were his solutions for covering the unemployed and uninsurable and tort reform and anti-trust relief. I have been told by a governor who was present at a closed meeting with the President that tort reform and anti-trust relief are elements of the President's plan in keeping with the message that Mrs. Clinton took to the AMA House of Delegates in June.

At the conclusion of Mr. Clinton's speech a singular thought kept running through my mind. It struck me how much the President had matured concerning his approach to solving the nation's health care dilemma. I still remember his pre-election solutions as being very over-simplified compared to the complexity of the issue. It is clear that deliberations of the Clinton Task Force have brought a strong dose of reality about the extreme complexity of our health care system to the administration and that reasonable minds were changed accordingly. It is also striking how close the elements of Mr. Clinton's plan come to matching those of the AMA's Health Access America plan.

I anticipate that by the time this September issue is printed, Mr. Clinton will have unveiled all the details of his plan, and I certainly hope that those details will not alter the basic concepts of the plan he outlined in August.

The single most important element of his plan will be the detailed recommendations for financing health care for the unemployed and uninsurable members of our society, and I am sure that element will be at the core of very heated debate.

Be that as it may, from what we know today, it would appear that our efforts to design our state's health care system and to develop an association-sponsored, doctor-owned insurance entity will not only be possible but actually do-able. Both of these projects are proceeding quite efficiently, due to the dedicated efforts of many of our members. These tasks have required a great deal of time and effort and I am truly grateful to those who have unselfishly answered my call.

G. Lance Miller, MD

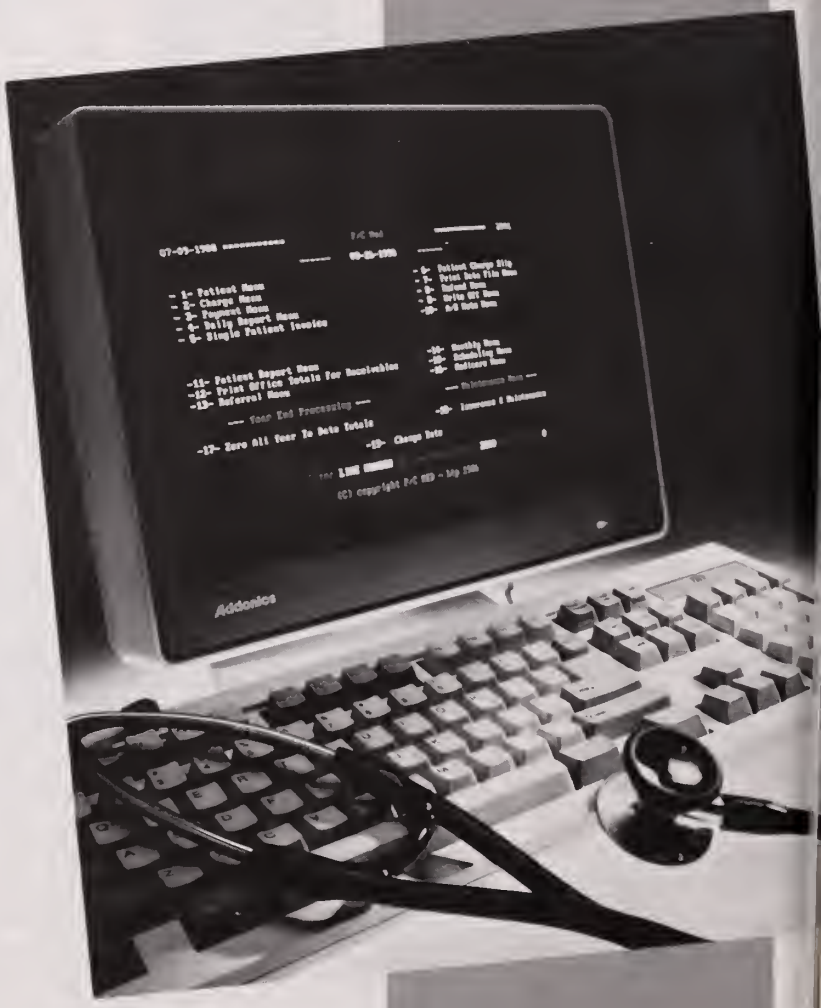
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Methicillin-Resistant *Staphylococcus aureus:*

Long-Term Routes of Acquisition in Hospital Patients

D.J. Flournoy, PhD; L.J. Davidson, MN, RN

Five hundred fifty three patients and two personnel (1986-1991) were categorized according to acquisition route of methicillin-resistant *Staphylococcus aureus* (MRSA) and initial culture date. Of the 555, there were 218 with nosocomial infections, 100 with nosocomial colonizations, 92 with community-acquired infections, and 145 with community-acquired colonizations. Nosocomial infections occurred significantly more often than nosocomial colonizations, community-acquired infections, or colonizations ($p<0.001$). Results of this study show that over a long period, our patients acquired MRSA by different routes, none of which were related to seasons of the year. Although seasonal outbreaks of epidemic MRSA are important, an awareness of the occurrence of endemic MRSA is also important because it serves as a reminder that MRSA reservoirs are continuously present in some institutions.

ALTHOUGH THERE ARE A NUMBER OF STUDIES ON the epidemic[1-8] and endemic[9] occurrence of methicillin-resistant *Staphylococcus aureus* (MRSA), there is a paucity of information regarding the long-term acquisition of MRSA by different routes (i.e., nosocomial versus community acquired, infection, and colonization). Indeed, most institutional reports on MRSA pertain to epidemics and may leave the impression that only epidemic MRSA are of importance. However, colonized patients and personnel represent sources in which others may become colonized or infected. We have reported on an outbreak of MRSA which occurred at our hospital in 1986-87.[10] However, the short study period and few cases in our report did not allow for a comprehensive comparison of MRSA acquisition routes—nor did it examine long-term seasonal occurrence. In light of the increase of MRSA in health care institutions,[11,12] we felt it might be helpful to compare all MRSA acquisition routes and determine if acquisition showed any trends towards seasonal variation.

From the Laboratory Service, Veterans Administration Medical Center, and the Department of Pathology and College of Nursing, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma 73104.

Direct correspondence to D.J. Flournoy, PhD, VAMC (113), 921 Northeast 13th Streeet, Oklahoma City, OK 73104.

Materials and Methods

This retrospective, descriptive study was performed in a 389-bed, tertiary care, general medical and surgical teaching institution primarily serving adult male veterans. The study period was 1986 through 1991. Demographic data on our patients[13,14] have been noted in earlier reports.

Five hundred fifty-three consecutively occurring patients and two personnel with cultures positive for MRSA were classified as nosocomial or community acquired and as representing colonization or infection by three infection control nurses, according to Centers for Disease Control guidelines.[15] All of these occurrences represeted new cases (i.e., first time documented/discovered) of MRSA acquisition. Nosocomial acquisition occurred when a patient acquired MRSA after three or more days of hospitalization. Community acquisition occurred when MRSA was isolated during the first two days after admission. Acquisition of MRSA from a nursing home was counted as community acquired.

Infection was defined by the occurrence of a posi-

tive culture/screen and the presence of clinical manifestations of disease as diagnosed by a physician and noted in the medical record. Colonization was defined as a positive culture/screen with no clinical manifestations noted. The following abbreviations were used: CC (community acquired colonization), CI (community acquired infection), NC (nosocomial colonization), and NI (noscocomial infection). The acquisition status (e.g., CI) was determined at the time of initial isolate identification.

Following an increase of surgical wound infections caused by MRSA, screens to detect colonization or infection were performed on many incoming nursing home patients, in-patients, and personnel.[16-18] MRSA were defined as *Staphylococcus aureus* which were resistant to oxacillin as determined by disc-agar diffusion testing. MRSA were isolated from sputum, blood, urine, and wound specimens received in the microbiology section. Cultures were incubated for a minimum of 48 hours at 35°C in room atmosphere.

Results

Table 1 notes the number of patients with MRSA which were isolated in each category by month and year. Descriptive statistics were performed on the data. For each of the acquisition categories in Table 1, data were examined for normalcy. There were no disproportionate values at a level of three standard deviations. For each of the acquisition categories in Table 1, data were also grouped by season of the year (e.g., December-February, March-May, June-August, September-November). Chi-square was performed with no significant differences noted among any of the acquisition categories by season.

When MRSA acquisition categories were reviewed, there was a significant difference (Chi-square = 77.95, df = 3, $p < 0.001$) among categories. Further examination revealed a significant difference between NI and all other categories (Chi-square = 21.00, df = 1, $p < 0.001$). There was an increase in colonizations and a decrease in infections during the study period.

Following an increase of surgical wound infections caused by MRSA, screens of nares and wrists were routinely performed on selected groups of personnel (10-40 physicians and nurses on two occasions) and on in-house and newly admitted patients. There were 0 MRSA screens in 1986 and 1987, 109 in 1988, 2,138 in 1989, 293 in 1990, and less than 25 in 1991. Less than 2% of the screens on personnel and 4% on patients were positive. The number of MRSA patients admitted from nursing homes was 5 in 1986, 18 in 1987, 22 in 1988, 62 in 1989, 34 in 1990, and 28 in 1991.

Discussion

Several factors undoubtedly influenced the increased occurrence of MRSA at our hospital, including a number of nursing home patient admissions and an increase of MRSA. During the study, many of the MRSA were isolated from patients who were admitted from nursing homes, a group with an unusually high proportion of MRSA.[11,12] During the period from 1986 through 1991, policies regarding nursing home residents and MRSA changed. In 1989, nursing homes were reluctant to take back their residents if, after hospital admission, they were found to be colonized with MRSA.

In April 1990, the Oklahoma State Department of Health issued a policy statement addressing MRSA, entitled "Guidelines for the Control of Methicillin-Resistant *Staphylococcus aureus* in Acute and Extended Care Facilities." This policy statement said that MRSA colonization was not an indication for hospitalization, but infections should be handled on a case-to-case basis. Following release of the statement, better cooperation between our hospital and nursing homes has resulted in a decrease in the admission of colonized patients to our hospital and refusal to accept those patients back in the nursing home.

Finally, in 1990, the routine method of managing MRSA patients was changed from strict isolation to private room without isolation. This policy change did not increase the number of patients developing NI with MRSA, as was feared by some. During the study period, there was no cohorting of MRSA patients. Nursing home admissions, screening for MRSA, patient management policies, and periodic outbreaks all influenced our data, and are common occurrences in an institutional/clinical setting.

During the study period, infections appeared to be decreasing while colonizations were increasing. This increase in colonizations may simply reflect a steady rise of methicillin resistance in the community as evidenced by increases in the occurrence of MRSA among hospitalized patients and nursing home residents.[11,12] In 1991, 46% of our *Staphylococcus aureus* isolates were resistant to methicillin.

With this large endemic population of MRSA, strategies for prevention and control of MRSA are different than those of an institution with a small population of MRSA. For example, it is impossible to place every patient in isolation if there are more patients with MRSA than there are isolation rooms. In addition, we have a sizeable pool of incoming MRSA, as evidenced by the fact that 43% of our MRSA were community acquired during the study period.

This study shows that of 553 patients and two per-

Table 1. Number of MRSA Patients by Acquisition Category, Year, and Month

Class	Year	Number of Patients with MRSA by Month: Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	All
CC	1986	0	0	0	0	0	0	0	0	0	0	1	0	1
	1987	2	1	0	2	0	0	0	0	1	0	0	0	6
	1988	0	0	0	0	0	0	1	1	0	0	0	1	3
	1989	0	3	2	2	3	4	1	5	4	4	4	3	35
	1990	4	6	10	5	4	4	4	1	3	6	3	4	54
	1991	2	2	3	5	1	2	5	3	3	8	7	5	46
	Total	8	12	15	14	8	10	11	10	11	18	15	13	145
CI	1986	0	0	0	0	0	0	0	1	1	1	1	3	7
	1987	1	1	2	3	2	2	1	0	4	1	1	2	20
	1988	1	1	0	3	2	1	0	2	1	0	4	1	16
	1989	3	1	3	2	1	2	1	4	4	1	4	1	27
	1990	1	2	1	0	2	2	1	1	2	1	0	2	15
	1991	0	0	1	0	0	0	1	0	0	0	3	2	7
	Total	6	5	7	8	7	7	4	8	12	4	13	11	92
NC	1986	0	0	0	0	0	0	0	0	0	1	2	1	4
	1987	1	0	0	0	3	1	2	0	0	0	0	2	9
	1988	0	1	0	0	0	2	0	1	0	0	0	2	6
	1989	4	0	1	3	3	0	0	0	0	2	1	1	15
	1990	0	0	0	3	0	4	0	5	2	4	2	3	23
	1991	6	1	3	7	6	1	1	3	4	3	4	4	43
	Total	11	2	4	13	12	8	3	9	6	10	9	13	100
NI	1986	0	0	0	0	0	1	2	1	1	5	7	3	20
	1987	6	2	6	4	2	2	3	2	2	1	1	0	31
	1988	1	2	3	7	7	5	3	2	2	3	5	16	56
	1989	14	13	9	7	2	2	3	5	2	7	5	1	70
	1990	3	3	1	2	2	0	4	4	2	1	1	1	24
	1991	3	2	0	2	2	0	2	2	2	1	1	0	17
	Total	27	22	19	22	15	10	17	16	11	18	20	21	218
	All	52	41	45	57	42	35	35	43	40	50	57	58	555

Total MRSA: 1986 (32), 1987 (66), 1988 (81), 1989 (147), 1990 (116), 1991 (113)
Mean number of MRSA/month by category: 12.1 (CC), 7.7 (CI), 8.3 (NC), 18.2 (NI)
Jan (January), Feb (February), Mar (March), Apr (April), Jun (June), Jul (July), Aug (August), Sep (September), Oct (October), Nov (November), Dec (December), NI (nosocomial infection), NC (nosocomial colonization), CI (community-acquired infection), CC (community-acquired colonization)

sonel, 57% (39% NI, 18% NC) acquired MRSA in the hospital. There was a significant number of nosocomial infections as compared with other acquisition routes. Because nosocomial infections represented a large proportion of all cases and because MRSA were not acquired more often during any season of the year, hospital personnel need to consistently practice strict/effective infection control measures (e.g., hand washing, specimen handling) in order to prevent the spread of this organism. In the last few years the number of nosocomial infections appears to be decreasing and may reflect better infection control adherence at our hospital.

Our study shows that over a period of years, large numbers of MRSA are acquired, regardless of season, in the community and in the hospital—with some patients being infected and others colonized. Indeed, patients in all acquisition groups are important reservoirs of MRSA. Although seasonal outbreaks of epidemic MRSA are important, an awareness of the occurrence of endemic MRSA is also important because it serves as a reminder that MRSA reservoirs are continuously present in some institutions.

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Wilson's Disease:

A Diagnosis Made in Two Individuals Greater Than 40 Years of Age

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Wilson's disease is an autosomal recessive disease of copper metabolism which is widely recognized as a disease occurring clinically in children, adolescents, and young adults. Unrecognized and therefore untreated Wilson's disease in patients over age 40 is thought to occur either rarely or not at all. Two cases of Wilson's disease presenting at an age greater than 40 years are presented. The first is a 42-year-old Israeli woman who presented with fulminant hepatic failure. The serologic and biochemical investigations obtained at the time of her fulminant hepatic failure included copper studies which suggested the diagnosis of Wilson's disease, which was confirmed by an examination of the native liver following successful orthotopic liver transplantation. The second case is that of a 56-year-old white male who presented to the hospital with a three-year history of neurological dysfunction, pancytopenia, and mild splenomegaly. A battery of serologic and biochemical investigations suggested a diagnosis of Wilson's disease. The diagnosis was confirmed by quantitative hepatic copper estimation and the demonstration of Wilson's disease in three of his siblings, all of whom were diagnosed after the proband case had been identified. This man and his siblings have been treated with d-penicillamine, with remarkable improvement in their neurologic and hepatic function. The proband is currently well 11 years after his diagnosis was established. These two cases demonstrate that a diagnosis of Wilson's disease should be considered as part of the differential diagnosis of individuals in the fourth and fifth decades of life who present with unexplained liver disease.

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WILSON'S DISEASE (WD) IS AN INHERITED METABOLIC disorder characterized by accumulation of copper in the liver and brain[1,2] which usually presents either as hepatic disease or neurological dysfunction and, less commonly, both.[2,3] Patients with a hepatic presentation of the disease typically present as adolescents with either chronic liver disease or fulminant hepatic failure (FHF). Those with a neurologic presentation typically are older—in their early twenties or thirties.

It is now well recognized that WD can present with any of a wide array of disease manifestations and that there is no "classic" clinical presentation.[4,5] Establishing a diagnosis of WD early in the clinical course of the disease is important as appropriate medical therapy can be lifesaving and prevent irreversible neurologic and hepatic dysfunction in those with chronic disease[6-8] or orthotopic liver transplantation (OLTx) in those presenting with FHF.[9,10]

WD is widely recognized as a disease of children, adolescents, and young adults.[5,11-15] Few if any cases are recognized in patients older than age 40. Some clinicians have suggested that the diagnosis of WD need not be entertained seriously in those more than 40 years of age. Herein are reported two cases of WD presenting after the age of 40 years. The first presented as a case of FHF in a 42-year-old woman. The second case was a 56-year-old man hospitalized on the neurology service

who was seen as a hepatology consult for asymptomatic chronic liver disease.

Case Reports

Case 1. A previously fit and well, 42-year-old Israeli woman presented with a one-month history of rapidly progressive jaundice, ascites, and peripheral edema. Her past medical history was negative except for a report of migraine headaches. She was married, had four children, and had no family history of liver disease. She was taking no medication before the onset of her symptoms. Her initial evaluation in Israel documented cirrhosis with portal hypertension and, despite an extensive series of investigations, no etiology for her cirrhosis was determined.

Seven weeks after her initial presentation with jaundice, she had deteriorated to the point of advanced hepatic encephalopathy (grade 3). Following an episode of bleeding within her rectus muscle sheath following some minor trauma, she became fully comatose and was transferred to Presbyterian University Hospital (PUH), for OLTx with a diagnosis of FHF of an unknown etiology.

On admission to the hospital in Pittsburgh, she was in a grade 3 coma, deeply jaundiced, and found to have massive ascites. Hepatomegaly but no splenomegaly was noted on physical examination. The laboratory investigations obtained are reported in Table 1. An ultrasound examination of liver revealed massive ascites and a heterogeneous echogenic liver consistent with cirrhosis. All of her hepatic vessels were patent. A CT scan of her abdomen demonstrated ascites, splenomegaly, and an abdominal wall hematoma. A CT scan of her head was interpreted as being normal without any mass effect. An eye examination without a slit lamp failed to demonstrate Kayser-Fleischer rings.

Her coma deepened over the next three days. Ultimately a diagnosis of FHF due to WD was made on the basis of biochemical measures of copper metabolism, a low serum uric acid, and hemolysis (Table 2).

Six days after her transfer to Pittsburgh, she underwent OLTx. Forty-eight hours after OLTx, her mental status had improved dramatically. A histopathological examination of the native liver to include rhodamine staining and quantitative hepatic copper determinations confirmed the diagnosis of WD.

Subsequently her liver function and neurological status deteriorated again over a four-week period and serial liver biopsies demonstrated severe acute rejection which did not respond to increased immunosuppression with both high dose steroids and OKT3. Because of increasing graft failure, she underwent retransplantation 30 days following her first transplant. By the end of second postoperative week, she was fully awake and conscious. Twelve weeks after her second OLTx, she had completely normal hepatic function and a normal neurologic examination.

Table 1. Routine Clinical Studies Obtained on the Two Cases

Investigation	Case 1	Case 2
Hemoglobin (g/dl)	12.8	15/—
White cell count (cells/mm^3)	4100	3000
Platelets (cells/mm^3)	42,000	108,000
Mean corpuscular volume (fl)	95.6	99
Reticulocytes (%)	9.9%*	—
Total bilirubin (mg/dl)	48	0.2
Alkaline phosphatase (iu/L)	117	107
Gamma-glutamyl transferase (iu/L)	62	140
Alanine amino-transferase (iu/L)	139	50
Aspartate amino-transferase (iu/L)	70	18
Prothrombin time (secs)	20.1	12
Albumin (G/dl)	4.1	3.0
Ammonia (umol/L)	166	—
Uric acid (mg/dl)	0.8	4.9
Haptoglobulin (mg/dl)	3	—

*Absolute reticulocyte count 247,500/mm^3 and Coombs test - negative

Table 2. Studies of Copper Metabolism in the Two Cases Reported

Investigation	Case 1 (Age 42)	Case 2 (Age 56)
Serum copper (mg/dl)	122 (60-90)*	36
Ceruloplasmin (mg/dl)	16.1 (16-29)	2.5
24-hour urinary copper (mg/total volume)	5751 (20-65)	126
Quantitative liver copper (mg/g dry weight of liver)	394 (20-45)	1256
Kayser-Fleischer rings (present or absent)	absent	absent

*Values in parentheses indicate normal range for the laboratory

Case 2. A 56-year-old white man presented with a three-year history of right upper quadrant discomfort, bloating, fatigue, slurred speech, blurring of vision, impaired memory, and wobbling gait with a tendency to fall. He had been investigated three years earlier at two different hospitals. A review of the records from those two hospitals showed that he had: (1) a mild pancytopenia with a normal bone marrow examination; (2) non- caseating granuloma and cirrhosis with a totally negative panel of hepatitis serologies; (3) cerebellar signs with a normal CT scan of his head and a normal cerebrospinal fluid examination; and (4) hypouricacidemia (2.0). All other biochemical, immunological and hematological investigations were normal. He was on no medications. His past medical history was otherwise negative.

His general physical examination was remarkable for an absence of red palms, spider angiomata, and jaundice. Neurological examination showed him to be alert and well oriented but experiencing dysarthria and a mild impairment of recent memory. He could not perform tandem walk. There were no other focal neurological signs. An abdominal examination showed no hepatomegaly, but a spleen tip was palpable. Ascites was absent. No Kayser-Fleischer rings were noted. A slit lamp examination was not performed, however.

Some of the laboratory investigations obtained on the patient are listed in Table 1. At peritoneoscopy, he was found to have a micronodular cirrhosis. A liver biopsy obtained at the time of laparoscopy was interpreted as showing cirrhosis and chronic active hepatitis. Rhodamine staining was performed and was markedly positive. A diagnosis of WD was made on the basis of the copper studies shown in Table 2. D-penicillamine was prescribed, with a significant resolution of his symptoms. Specifically, his dysarthria and ataxia resolved completely. He has been maintained on d-penicillamine ever since, with a return of near normal neurological function.

Discussion

These two cases highlight pitfalls of placing undue emphasis on the patient's age at presentation of liver disease. Both patients were positively shown to have WD and the diagnosis in each was delayed considerably because their age was considered initially to have excluded the possibility of WD. This initial error in the clinical assessment of these two patients occurred as a result of the referring physician's interpretation of the report by McCullough et al, wherein it was suggested that FHF in a patient with an age greater than 30 years is unlikely to be a result of WD.[11] While this may be true in most cases, as shown by their report, age alone should not exclude a diagnosis of WD. At least five individuals age 50 or older with WD have been reported prior to this report. Werthermann[16] and Lüthy[17] reported a total of three patients in whom the diagnosis was made at autopsy when the patients had been age 51, 66, and 66 years respectively. More recently, Strickland and Leu[18] reported a 50-year-old who presented with neurologic complaints and who ultimately was found to have Wilson's disease. Similarly, investigators at the Mayo Clinic have reported on two occasions[2,19] the same male who at the time of diagnosis was 57 year old with complaints of fatigue, hypersplenism with leucopenia, thrombocytopenia, hemolysis, and clinical cirrhosis. Thus, prior to this case, only two living subjects have been reported in whom the diagnosis of WD was established and treatment started after the age of 50 years.

The diagnosis in Case 1 was made more difficult because of a low "normal" ceruloplasmin and a "normal" serum copper level obtained as a result of the patient's initial biochemical screening procedures. It is important to recall that this combination of biochemical findings in WD is not unusual in cases of fulminant WD and has been well described.[16,17,20,21] Thus such findings should not deter one from pursuing a diagnosis of WD with both a 24-hour urinary copper determination and quantitative hepatic copper estimate. Other clues such as hypouricacidemia, hemolysis[19,21] and a very high bilirubin with a normal alkaline phosphatase[20] in the setting of FHF should alert the physician to the possibility of a diagnosis of WD. It is important to note that Kayser-Fleischer rings can be absent in WD[14,16,17] and were in both of the cases herein reported, although their absence in these cases was not confirmed by a slit lamp examination. Thus the failure to find a Kayser-Fleischer ring does not rule out the diagnosis of WD. Conversely, Kayser-Fleischer rings occur occasionally in non-Wilsonian liver disease.[17,20]

In Case 2, the diagnosis of WD was made three years after an initial investigation of the cause of the patient's neurologic symptoms had failed to determine the actual cause of his complaints. This delay in establishing a diagnosis occurred as a result of a mistaken assumption by his physicians that the patient was too old to have WD despite the fact that he manifested evidenced for combined hepatic and neurological dysfunction. The critical points in this second case were that three younger siblings also had clinical evidence for both hepatic and neurologic diseases and all three, with the proband, were found to have markedly increased levels of hepatic copper. Moreover, each responded dramatically to d-pen-

icillamine therapy with improvement in their hepatic and neurological dysfunction. On d-penicillamine, the second case has remained well for 11 years. It is particularly important to note in this case that therapy with d-penicillamine not only resolved the chronic neurologic symptoms, but has prolonged the patient's survival well into his late 60s.[15]

It's well known that patients with WD presenting with hepatic disease, either with or without neurological dysfunction, experience a high mortality rate unless treated aggressively with decoppering agents.[3,15] Thus establishing a diagnosis of WD and doing so early can be critically important. Several algorithms have been made to enable physicians to make a quick yet definitive diagnosis of WD in the setting of FHF using standard clinical and laboratory data.[3,11,12,20-25] The most recent of these have been the alkaline phosphate to total bilirubin ratio and the AST/ALT ratio.[21] Interestingly, in Case 1, neither criteria was diagnostic of WD but was highly suggestive of the diagnosis. Nonetheless, the serum copper, urinary copper, and hepatic copper measurements established the correct diagnosis in both cases. Thus although many biochemical measures are known to be abnormal in patients with Wilson's disease, the two most reliable remain the 24-hour urinary copper determination and the hepatic copper content assessed quantitatively. In considering a diagnosis of Wilson's disease, one has to remember that the biochemical markers of the disease depend upon the stage of the disease and that the clinical presentation and stage of the disease need to be considered in the diagnostic evaluation of patients. Nonetheless, the three best markers of the disease are: the 24-hour urinary copper level, the hepatic copper content, and the presence of Kayser-Fleischer rings.

These two cases not only highlight the fact that WD can present in an individual older than 40 but also clearly document that the full clinical spectrum of WD ranging from FHF to demonstrable neurologic dysfunction occurring in an individual with established cirrhosis can be seen in older individuals.

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Domestic Violence—Battered Woman Syndrome

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Domestic violence is extremely widespread and often goes unrecognized by physicians. The problem is discussed and ideas for dealing with it are outlined.

DOMESTIC VIOLENCE IS A PROBLEM OF VAST proportions—one that many physicians are reluctant to confront. Some statistics indicate it may be a more common cause of injury to women than automobile accidents, muggings, and rape combined.[1] Indeed, according to the former United States Surgeon General, because of domestic violence the home is more dangerous than the streets for women.[2]

Jones noted that with an incidence estimated at 6 million women each year, this problem has become epidemic and can no longer be disregarded.[3] Thirty percent of female homicide victims are killed by their husbands or boyfriends. Jones has encouraged all members of the American College of Obstetrics and Gynecology to adopt a program (outlined below) to deal with this problem.

Discussion

There is some feeling that women who are battered "bring it on themselves," or that if it were bad enough they would contact the police. However, many of these women have been programmed to accept a lower role in the family and have low self-esteem. Furthermore, they usually are dependant on the batterer for financial support. They may have been led to believe that the problem is their fault.

Direct correspondence to Philip J. Maguire, MD, 1124 N.W. 50th Street, Oklahoma City, OK 73118.

The batterer will threaten them with further violence or even death if they reveal the problem. Walker, in an extensive study, revealed that batterers and victims proceed from abuse to suicide and homicide.[4] Furthermore, 11% of the victims attempted to kill the batterer.

Additional evidence of the scope of this problem is found in a Centers for Disease Control study.[5] The study relates that interpersonal violence is a problem with the same breadth and toll on public health and morbidity as cancer and heart disease.

Batterers tend to be excellent manipulators and have a contempt for women. They are experts in minimizing womens' roles. Violence is used by the most powerful family member as a means of legitimizing his position.[6] These family members resort to violence when they have physical power over the family but few resources, such as when they are unemployed or the lower wage earner. There is often associated substance abuse.

Treatment

As with most disease processes, the ability to recognize cases depends on having a high index of suspicion. Often the history is inconsistent with the extent or location of the injuries. Most trauma is around the head, neck, breasts, abdomen, and upper extremities. Depression is a common accompaniment. A high percentage of cases seen in the ER are not recognized as domestic violence.[8] Prenatal screening is widely recognized as important in the early detection of disorders such as diabetes, hypertension and toxemia. Unfortunately, it is not used to discover physical abuse.[9]

An openness in broaching the subject with victims is appropriate. Pose questions such as, "Have you ever been hurt at home?" There is frequently a reluctance to discuss the injuries. History taking must be nonjudgmental. The victims are often embarrassed and can be very evasive. If the patient does not want to pursue the discussion or demonstrates fear, it is important to at least make her aware help is available. If possible, it is best to address the subject away from the probable batterer.

As indicated above, the American College of Obstetrics and Gynecology[3] has called for an all-out effort to address this problem. Their proposals are divided into four steps:

1. Development of medical training and examinations on domestic violence detection and treatment;

2. Production of educational materials for health professionals;

3. Development of adequate services and laws to protect battered women;

4. Raising of public awareness about the epidemic and of the domestic violence hotline number.

Summary

When aiding and counseling these women, it is important to see that they to have a plan. Such things as having clothes, money, and preparation for children are necessary. Being aware of available resources such as agencies dealing with the problem is foremost. Directing victims to appropriate agencies and providing support is essential. The National Coalition Against Domestic Violence has a 24-hour Hotline: 1-800-333-SAFE.

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The Authors

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National Network of Libraries of Medicine and Health Science Libraries in Oklahoma

Deborah D. Halsted and Clinton M. Thompson

Rural physicians have access to a considerable variety of medical library resources, despite their outlying practice locations. This article outlines some of the sources available and how they may be reached.

IN MAY 1991, THE HOUSTON ACADEMY OF MEDICINE–Texas Medical Center Library (HAM- TMCL) was awarded a five-year contract from the National Library of Medicine (NLM) to serve as the Regional Medical Library (RML) for the South Central Region (SCR) of the National Network of Libraries of Medicine (NN/LM). The focus of the RML staff, along with the staff at seven other medical libraries across the country and the staff at the National Network Office at NLM, is to improve access to biomedical information for health professionals nationwide.

The NN/LM network was established by the Medical Library Assistance Act in 1965 (Public Law 89-291) which authorized NLM to fund already established medical libraries to serve as RMLs for specific geographic areas. Currently the network includes eight RMLs, over 130 resource libraries (mostly in academic medical libraries), and over 3,000 primary access libraries (mostly hospital libraries). Region 5, the region covered by the HAM-TMCL (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas), has fifteen resource libraries and over 300 primary access libraries. In 1988 Dr. Michael E. DeBakey of Baylor College of Medicine was asked by the NLM Board of Regents to chair an Outreach Planning Panel. The purpose of the panel was... "to find techniques for disseminating to health professionals the information they need to minister to their patients in the most efficient and effective way possible."[1] This panel found that the most common problem for health professionals, especially in rural areas, was access to information. Some of the recommendations made by the panel were to build a more active network of medical libraries, to reach out to all health professionals, especially those in areas which do not currently have access to a medical library, and to actively promote the products and services of the NLM.

Libraries

In Oklahoma a strong network of medical libraries has existed for many years. There are three resource libraries in the state: University of Oklahoma Health Sciences Center, Robert M. Bird Health Sciences Library in Oklahoma City; University of Oklahoma College of Medicine, Tulsa, Library in Tulsa; and Oklahoma College of Osteopathic Medicine, Medical Library, also in Tulsa. All three of these libraries are dedicated to outreach, not only to health professionals in Oklahoma City and Tulsa, but throughout the state.

In addition, other health science libraries in Oklahoma have created a strong network or consortium through which they are able to join forces in serving the needs of the health professionals in their geographical areas. The NN/LM SCR has funded two of these libraries, Baptist Medical Center in Oklahoma City, and Tulsa Regional Medical Center, to serve as access libraries, or

Direct correspondence to Deborah Halsted, Coordinator for Outreach, National Network of Libraries of Medicine, Houston Academy of Medicine, Texas Medical Center Library, 1133 M.D. Anderson Boulevard, Houston, TX 77030.

libraries which make a special effort to reach out to rural health professionals.

Grateful Med®

In 1986 the NLM developed a software package called Grateful Med which makes searching MEDLINE® (an online index of medical journals) and other NLM databases easy for health professionals. The software provides an input screen or template, and helps select appropriate search terms though an online thesaurus of controlled medical vocabulary called MeSH (Medical Subject Headings). Searches can also be made on authors' names or unique terms not in MeSH. After the search strategy is formulated, the searcher can choose to retrieve author-generated abstracts, to limit to the English language, and to print out the MeSH subject heading.

Once the searcher completes these steps, the Grateful Med software connects to the NLM computer and transmits the search commands. If the health professional lives in a metropolitan area, local telecommunication networks, such as Tymnet and Sprintnet, are used; therefore, no long-distance charges are accrued. If the searcher lives in a rural area, the NLM will provide an 800 phone number. After the search is run, the results are downloaded to the searcher's computer. Once the downloading is completed, and charges are no longer being accrued, the searcher can review the citations. Relevant citations can be printed or written to a file. Grateful Med can also analyze the citation selected as relevant and suggest terms from MeSH that may be helpful for future searches.

System requirements for the IBM version of Grateful Med are: 512K RAM available (640K recommended; DOS 3.0 or higher; 1.9-2.4 MB of free hard disk space; Hayes® SmartModem® or fully compatible modem, or direct access to Internet or a Novell® communications server. For the Macintosh, the requirements are: any of the Apple Macintosh computers with at least 1MB RAM; System 4.3 or higher; Hayes SmartModem or fully compatible modem, or direct access to Internet or a Novell communications server.

Besides MEDLINE, some of the other files searchable through Grateful Med include:

AIDSDRUGS—Substances being tested in AIDS-related clinical trials.

AIDSLINE®—AIDS and related topics.

AIDSTRIALS—Clinical trials of substances being tested for use against AIDS, AIDS-related complexes (ARC), AIDS-related opportunistic diseases, and HIV infection.

BIOETHICSLINE®—Ethics and related public policy issues in health care and biomedical research.

CANCERLIT®—Major cancer topics.

CCRIS—Chemical carcinogens, mutagens, tumor promoters, and tumor inhibitors.

ChemID® and CHEMLINE®—Dictionaries of chemicals.

HEALTH—Non-clinical aspects of health care delivery.

HSDB®—Hazardous chemicals; toxic effects, environmental fate, safety, and handling.

MEDLINE—Bibliographic file of biomedicine.

PDQ—Advances in cancer treatment and clinical trials.

RTECS®—Potentially toxic chemicals.

TOXLINE® and TOXLIT®—Toxicological, pharmacological, biochemical, and physiological effects of drugs and other chemicals.

TRI—Annual estimated releases of toxic chemicals to the environment and amounts transferred to waste sites.

In December 1992, the NLM lowered prices for access to all NLM databases. The average cost for a search through Grateful Med is approximately $1 to $2, considerably cheaper than searching through commercial databases.

Loansome Doc®

An exciting new feature of Grateful Med is Loansome Doc, a document ordering feature, which gives Grateful Med users quick and easy access to complete journal articles. From a list of retrieved citations, the user can select relevant articles to be ordered from a health science library. Once the health professional establishes an agreement with a library, the library will photocopy articles held in its collection, or, if requested by the health professional, will order any article not held locally. Loansome Doc makes it possible for all health professionals to have access to the same journal articles, no matter where they live. Through the use of a telefacsimile machine, even rural physicians can have information as quickly as those in an academic medical school.

Network of Libraries

The National Network of Libraries of Medicine is an important key in providing services to health professionals. All health professionals, especially those not currently affiliated with a health science library, should locate a library and make an agreement for services. All libraries in the network require an agreement with health professionals prior to providing Loansome Doc services and many of the other valuable services such as mediated searches, reference assistance, and emergency faxed articles.

(continued)

If you have a question as to which library would best serve your needs, call the NN/LM SCR at (800) 338-7657. Or, if you are in the western part of Oklahoma, you may contact the University of Oklahoma Health Sciences Center, Robert M. Bird Health Sciences Library. In the eastern part of the state, contact the University of Oklahoma College of Medicine, Tulsa, Library. Any DO in Oklahoma is welcome to contact the Oklahoma College of Osteopathic Medicine, Medical Library.

If you currently have privileges with a hospital that has a health sciences library, stop in and get to know the librarian. The library and your librarian can play an important part in patient care and continuing education. In an age when the health care field is changing so rapidly, it is imperative for health professionals to be affiliated with a library in order to keep abreast of the changes.

Hospital Libraries in Oklahoma

* Denotes FAX machine is not in library

Baptist Medical Center
Medical Library
3300 NW Expressway
Oklahoma City, OK 73112
(405) 949-3766
(405) 949-3883 FAX
Cheryl Suttles, Librarian

Children's Hospital of Okla.
Medical Library
P.O. Box 26307
Oklahoma City, OK 73126
(405) 271-5699
(405) 271-3017 FAX
Jeanie Cavett, Librarian

Deaconess Hospital
Library
5501 N. Portland
Oklahoma City, OK 73112
(405) 949-5581 x3308
(405) 949-6230 FAX
Jean C. Burrows, Librarian

Dean A. McGee Eye Institute
Library
608 Stanton L. Young Blvd.
Oklahoma City, OK 73104
(405) 271-6085
(405) 271-3013* FAX
Sheri Greenwood, Librarian

Griffin Memorial Hospital
Library
P.O. Box 151
Norman, OK 73070
(405) 321-4880 x2141
(405) 364-5340 FAX
Shirley Pierce, Librarian

Hillcrest Health Center
Library
2129 SW 59th St.
Oklahoma City, OK 73119
(405) 680-2189
(405) 680-2430 FAX
Walee Chotikavanic, Librarian

Hillcrest Medical Center
1120 S. Utica
Tulsa, OK 74104
(918) 579-8357
(918) 584-6636* FAX
Peggy Cook, Librarian

Jane Phillips Episcopal-
Methodist Medical Center
Medical Library
3500 E. Frank Phillips Blvd.
Bartlesville, OK 74005
(918) 333-7200 x512
(918) 333-1345* FAX

Laureate Psychiatric Clinic
and Hospital
6655 S. Yale Ave.
Tulsa, OK 74136
(918) 491-4006
(918) 491-8565* FAX
Jamey Carney, Librarian

Memorial Hospital of
Southern Oklahoma
Medical Library
1011 14th Ave., NW
Ardmore, OK 73401
(405) 221-6625
(405) 221-6599 FAX
Susan Mertes, Librarian

Mercy Health Center
Medical Library
4300 West Memorial Road
Oklahoma City, OK 73120
(405) 752-3390
(405) 752-3093* FAX
May Cordry, Librarian

Muskogee Regional
Medical Center
C. Oglesbee Medical Library
300 Rockefeller Dr.
Muskogee, OK 74401
(918) 682-5501
(918) 684-2392* FAX
Glenda Stubbs, Librarian

Norman Regional Hospital
Health Sciences Library
901 Porter, P.O. Box 1308
Norman, OK 73070
(405) 360-8385
(405) 321-6576 FAX
Michelynn McKnight,
Librarian

Oklahoma Medical Research
Foundation
O.B. Milligan Research Library
825 NE 13th St.
Oklahoma City, OK 73104
(405) 271-7567
Beth Mikkola, Librarian

Presbyterian Hospital
Medical Library
700 NE 13th
Oklahoma City, OK 73104
(405) 271-4266
(405) 271-6897 FAX
Mary Lou Tremblay, Librarian

Red Rock Mental Health Ctr.
Medical Library
4400 N. Lincoln
Oklahoma City, OK 73105
(405) 424-0354
Linda Temple, Librarian

Reynolds Army
Community Hospital
Medical Library
Bldg. 4300
Ft. Sill, OK 73503
(405) 351-0012
(405) 351-0599 FAX
Kathy Dexter, Librarian

St. Anthony Hospital
O'Donoghue Medical Library
P.O. Box 205
Oklahoma City, OK 73101
(405) 272-6284
(405) 272-7075 FAX
Sharon Jorski, Librarian

St. Francis Hospital
Library
6505 S. Yale
Tulsa, OK 74136
(918) 494-1210
(918) 494-1893 FAX
Elizabeth Richards, Librarian

St. John Medical Center
1923 S. Utica
Tulsa, OK 74104
(918) 744-2970
(918) 744-2177* FAX
James Donovan, Librarian

St. Mary's Hospital
305 Fifth St.
Enid, OK 73701
(405) 249-3092
(405) 249-3091 FAX
Janet Puckett, Librarian

Southwest Medical Center
of Oklahoma
Health Science Library
1001 SW 44th St.
Oklahoma City, OK 73109
(405) 636-7087
(405) 636-7197* FAX
Leona Petit, Librarian

Tulsa Regional Medical Center
Library #H230
744 W. 9th St.
Tulsa, OK 74127
(918) 599-5298
(918) 599-5829 FAX
Jane Cooper, Librarian

U.S. Air Force Hospital SGQL
Medical Library
Tinker AFB, OK 73145
(405) 734-8443
Beth Mills, Librarian

Valley View Regional Hospital
430 Monta Vista
Ada, OK 74820
(405) 332-2323
(405) 332-5686* FAX
Belinda McSwain, Librarian

Veterans Affairs Medical Ctr.
Medical Library
Honor Heights Dr.
Muskogee, OK 74401
(918) 683-3261 x240
(918) 683-0488 FAX
Glenda Stubbs, Librarian

Veterans Affairs Medical Ctr.
Medical Library
921 NE 13th St.
Oklahoma City, OK 73104
(405) 270-0501 x3688
(405) 270-5145 FAX
Chris Mitchell, Librarian

Resource Libraries in Oklahoma

Oklahoma State Univ. College
of Osteopathic Medicine
Medical Library
1111 W. 17th St.
Tulsa, OK 74107
(918) 582-1972 x351
(918) 582 6316 FAX
Anita Sutrick, Director

University of Oklahoma
College of Medicine, Tulsa
Library
2808 S. Sheridan
Tulsa, OK 74107
(918) 838-4616
(918) 838-4624
Janet Minnerath, Director

University of Oklahoma
Robert M. Bird Library
P.O. Box 26901
Oklahoma City, OK 73104
(405) 271-2672
(405) 271-3297 FAX
Clinton M. Thompson, Director

Other Libraries with Health Science Collections

J.D. McCarthy Center
Medical Library
1125 E. Alameda
Norman, OK 73070
Cathy Bennett, Librarian

Connors State College
Library
Route 1, Box 1000
Warner, OK 74469
(918) 463-2931 x269
(918) 463-2233* FAX
I.D. Kerley, Librarian

Federal Aviation Adm.
Civil Aeromedical Inst. Library
P.O. Box 25082
Oklahoma City, OK 73125
(405) 680-6804
(405) 680-4813
Kathy Wade, Librarian

Oklahoma State University
Veterinary Medicine Library
Stillwater, OK 74078
(405) 744-6655
(405) 744-5609 FAX
Pat Mullen, Librarian

Oral Roberts University
Library
7777 S. Lewis
Tulsa, OK 74136
(918) 495-6732
Peggy Pixley, Librarian

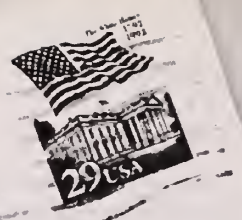
End Note

1. National Library of Medicine (U.S.). Board of Regents; *Improving Health Professionals' Access to Information*, Bethesda, MD, U.S. Department of Health and Human Services, 1989, p 2.

The Authors

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Clinton M. Thompson is director of the Robert M. Bird Health Sciences Library and professor in the Department of Medical Library Science in the College of Allied Health, University of Oklahoma Health Sciences Center, Oklahoma City.



Open Letter to President and Hillary Rodham Clinton-- This Time About Total Quality Management for Lawyers and About Running Courthouses Like Hospitals

Dear President and Mrs. Clinton:

I wrote you a month ago, but you haven't replied.

Perhaps you didn't receive my first letter [JOURNAL, June 93]. In that letter, I wrote to you as a doctor appealing to two lawyers. I asked you to persuade your legal brethren to make their fair share of sacrifice for the national good.

I made two modest proposals:

(1) that you appoint an MD to chair a national legal reform task force and to exclude the American Bar Association and American Trial Lawyers from the secret proceedings to plot the destiny of the legal profession; and

(2) that you set up a managed competition scheme for lawyers.

LAWYERS HAVEN'T RESPONDED

Physicians who read my first letter have applauded my proposals. But you and the other lawyers haven't responded.

I don't understand why not: I was simply pleading for you lawyers to make your fair share of sacrifice. I recommended managed competition, as applied to doctors, also be applied to lawyers. I suggested lawyers abolish fee-for-service payment, eradicate billing based on time spent on phone consultations, erase the pay differences among junior and senior partners, and stand in line and disallow favored health-care treatment among yourselves, your peers, or your relatives.

WHILE I'VE BEEN WAITING FOR YOUR REPLY

In any event, while I've been waiting for your reply to my first letter, I've come up with two more proposals for you to consider. I'm sure you'll like these two proposals even better than my first two proposals. The first guarantees total quality justice and the second maximal speedy justice.

PROPOSAL THREE—TOTAL QUALITY MANAGEMENT FOR LAWYERS

You lawyers should create a commission to introduce "Total Quality Management," or TQM, to the law profession. After all, if you're going to be part of a regional budget-managed, economically viable integrated legal delivery system, you're going to have to compete with your fellow lawyers on the basis of cost-effectiveness and documentable quality.

Otherwise, how is the public going to tell the "cost-effective" lawyers from the "exorbitant" lawyers, or the "good" lawyers from the "bad" lawyers? In other words, how is the public going to judge your "value," as defined by quality of your services for the price of the service rendered?

Oh, I know this business of being judged on quality—on your level of customer ser-vice, your teamwork to improve products, and your quantifiable results—will be tough on you.

Your smarts, your skills, and your political savvy will become irrelevant. To put it another way, legal judgment will become about as important as clinical

judgment. A lot of joy will go out of the practice of law. But I'm sure you'll agree the public needs some measure of quality to judge your performances. How else are we going to know whether we should retain your trust or pay your fees?

Proposal Four—Run the Courthouse Like a Hospital

My last proposal is the most modest of all—that lawyers run courthouses like hospitals and put courthouses under similar state and federal regulations.

You can start by keeping courthouses open 24 hours a day. Our society deserves swift justice. We need judges on call 24 hours a day so they can mete out sentences with terrible swift speed. Besides, having judges on call 24 hours a day will unclog all that backlog you have in the court system.

This constant judgmental vigilance will necessitate that many of you judges work round the clock, but you've always been clock watchers anyway. So being always on call should not be a problem.

Just set up a 24-hour call schedule for judges and lawyers like we doctors do for ourselves. And please wear your beepers. Jeepers creepers, we may need to get hold of you instantaneously for some legal-threatening situation.

Legal Problems Are Like Medical Problems

Legal problems are like medical problems. They can occur at any time of the day or night. Mayhem, murder, rape, assault, domestic violence, drunken driving, and theft don't respect time. These acts must be dealt with in a timely fashion if we are to have speedy resolution of these dastardly deeds.

Maybe, just maybe, if our legal system were to act decisively, quickly, and with less permissiveness, we could turn around our deteriorating violent crime rate.

Year	Violent Crime Rate (per 100,000)*
1960	16.1
1965	20.0
1970	36.4
1975	48.8
1980	59.7
1985	53.3
1990	73.2
1991	75.8

*Violent crimes include murder, rape, robbery, aggravated assault, burglary, larceny, and motor vehicle theft.

On Staffing the Courthouse on a 24-Hour Basis

Staff the courthouse 24 hours a day, and be sure to have legal aides—let's call them "lurses"—always on duty. In case things get out of hand, you may need another 24-hour type of person. Let's call them "disorderlies."

And by all means, keep your emergency legal clinic open at all times with a lawyer always on hand to receive all comers, especially those who can't pay—those on Legiaid, a new federal program to cover the poor, and Legicare, a new program to protect the elderly. And no dumping please—you must take care of all, regardless of their ability to pay, regardless of the time of day or night.

A Joint Commission for the Accreditation of Courthouses

Finally, I suggest you create a Joint Commission for the Accreditation of Courthouses. You can never tell when a lawyer, or a lurse, or a disorderly, or any other person in the courthouse might stray off the beaten legal path and endanger a client by failing to write up a procedure, follow a manual, abide by a rule, affix a signature, observe a right, or otherwise not do something strictly by the book.

It's procedures—not results, not justice, not fairness—that define a good courthouse. Meeting the specifications, mandates, and dictates of the Joint Commission for the Accreditation of Courthouses may run up your expenses by 25 percent or so. But what the hell, it's taxpayers' money, and besides, as lawyers you've never met a bureaucracy you didn't like.

Concluding Remarks

That's all the proposals I have for now. By the way, we doctors are still breathlessly waiting for your big proposal to solve the health-care crisis.

I've been thinking about what you need to do to sneak your proposal by the health-care establishment (who, God forbid, might have constructive advice to offer) and to get your proposal by those Republican Congressional watchdogs.

My advice boils down to three fundamentals:

- KISS (Keep It Secret, Stupid)
- HPIC (Herd Physicians Into Cooperatives)
- HCFA (Hillary Can Fix Anything)

And never forget. Yours is the politics of virtue. You define the public good. Only you know what the public needs. You are right, and your critics are

wrong. Never compromise. Never ask for advice from those engaged in health care.

Remember: You can do anything you want no matter what the opposition and the public thinks. You are *World Clash Politicians* and *World Clash Lawyers*. You are adversarial masters and masters of your adversaries.

With all of these virtues and skills, I'm sure you and your lawyer friends will be evenhanded in reforming your profession. I am confident you and your lawyer friends will make your fair share of sacrifice, including massive fee cuts, to balance the budget. I apologize for the length of these two letters. I should have followed the advice of a lawyer friend of mine: always keep your briefs down.

Your Humble and Obedient Servant,
—Richard L. Reece, MD
Oklahoma City

Note: Dr. Reece is the former editor-in-chief of *Minnesota Medicine*. A pathologist, he now practices in Oklahoma City and continues to publish a monthly newsletter, *The Reece Report*.



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James C. Slater, M.D.	Campbell Clinic trained; Full Fellowship Speciality in Arthritis Surgery; Harvard/Tufts

Violence becomes a public health issue in Oklahoma

Adopting the approach that violence in our society can be treated as a public health problem rather than a crime-and-punishment issue, the Oklahoma Legislature has established the Oklahoma Committee on Violence and Public Health. The 11-member group is charged with developing violence prevention strategies within the state and will be administered through the College of Public Health at the University of Oklahoma Health Sciences Center (OUHSC) in Oklahoma City.

"The committee members already recognize that health programs alone cannot deal with the determinants of violence and abusive behavior," says Dr. Bailus Walker, committee chair and dean of the college. "So, in the formulation of prevention strategies, many major aspects of our social structure must be considered—the family, the community, the educational system, and the economic structure."

The committee's formally outlined goals include:

- Establishing the reduction of violence in Oklahoma as a state goal
- Examining and studying the causes of violence in Oklahoma
- Communicating with public health specialists, medical care specialists, and other professionals in order to become better informed about violence-related issues
- Making recommendations for the provision of violence prevention services in the various urban and rural communities in the state
- Developing strategies of public health models for reducing violence in Oklahoma
- Recommending adjustments to the health and medical research system's domain to include more areas of direct relevance to the violence epidemic.

Serving with Walker on the committee are Douglas Voth, Executive Dean, University of Oklahoma College of Medicine; Thomas Wesley Allen, Provost/Dean, Oklahoma State University College of Medicine–Tulsa; Edward Brandt, Jr., Professor and Co-Director, Center for Health Policy and Research Development, University of Oklahoma College of Public Health; Thomas Peace, Commissioner of Health, Oklahoma State Department of Health; Benjamin Demps, Jr., Secretary, Department of Health and Human Services; Larry Fields, Director, Department of Corrections; Sharon Boehler, Commissioner, Department of Mental Health and Substance Abuse Services; Sandy Garrett, State Superintendent of Public Instruction; Julia Norlin, Director, University of Oklahoma School of Social work; and Dave McBride, Commissioner, Department of Public Safety.

"Thirteen of the nation's 20 most populated cities



Oklahoma physicians in Chicago were honored by the AMA for their work in the Outreach membership program. AMA House Vice Speaker Richard F. Corlin, MD, (l) congratulates Sara R. DePersio, MD, Oklahoma City, and John B. Nettles, MD, Tulsa. Also recognized was Perry A. Lambird, MD, Oklahoma City. Drs. DePersio and Lambird were in Chicago in June as members of the Oklahoma delegation. Dr. Nettles was a delegate for the American College of Obstetricians and Gynecologists.

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National Practitioner Data Bank to add fee for self-query

Effective July 1, 1993, National Practitioner Data Bank (NPDB) query fees increased from $6 to $10 for paper claims. Electronic queries remain at $6. By late 1993, the NPDB also plans to begin imposing a fee for physician self-queries, which are currently processed free of charge. Physicians, however, still will receive free copies of reports reports filed with the NPDB.

The NPDB also plans to begin allowing physicians to comment on information submitted about them to the NPDB.

At its annual meeting in June, the AMA House of Delegates adopted a resolution calling for the AMA to strengthen its fight to dissolve the National Practitioner Data Bank.

The move further encourages the AMA to convince Congress to repeal legislation authorizing the data bank.

The House of Delegates called for the AMA to affirm its support for the Federation of State Medical Boards Action Data Bank. Testimony was strongly in favor of the AMA and the medical profession to take a more aggressive role in policing itself.

The Oklahoma State Medical Association Hospital Medical Staff Section (OSMA-HMSS) has maintained a strong stance for the dissolution of the National Practitioner Data Bank beginning with its inception in 1986 as part of the Health Care Quality Improvement Act of 1986. We also have tried to encourage the AMA Board of Trustees to continue to work together with the Federation of State Medical Boards' Data Bank and the AMA National Physician Credentials Verification Service, thus offering a more accurate and meaningful data bank for both positive and negative information.

The recent developments at the annual meeting of the AMA House of Delegates are encouraging.

—William O. Coleman, MD
Chair, OSMA-HMSS

Health Department

Animal Bite Update

Warm weather brings both people and animals to the great outdoors for summertime activities. Sometimes this combination can create a confrontation which results in an animal bite.

Besides the obvious risk of a secondary bacteria infection, there are other considerations that warrant attention. Rabies and tetanus exposure are more likely possibilities from an animal bite; however, other diseases carried by exotic animals, such as simian B virus carried by Old World monkeys, are sometimes passed to humans though a bite.

The Oklahoma State Department of Health (OSDH) and local health departments can be a valuable resource to the practicing physician in the management of theses exposures. The local health department or epidemiologist should have access to the most up-to-date information concerning exotic and common animal viruses.

Since the State Commissioner of Health has the authority to order an animal to be quarantined and euthanized, the OSDH has developed an investigation procedure working with the attending physician to determine what action should be taken in cases of possible exposure to rabies as well as other viruses. The investigation procedure begins with a verification of the animal type, verifying the behavior of that animal before and after the biting incident, and determining the severity and the physical site of the bite. OSDH recommendations will depend on these factors.

The Oklahoma State Board of Health has recently approved a clarified version of rabies regulations that simplifies the terms for management and enforcement. Instead of suggesting that all animals would be investigated under the same process, the regulations specify that appropriately immunized cats and dogs should be evaluated for unusual behavior after a biting incident. This is specific to dogs and cats because there is more information available concerning their virus in-

Violence committee *(continued)*

endured double-digit increases in violent crimes in 1992," Walker notes. "And according to a recent edition of the *Journal of the American Medical Association,* this violence indicates that Americans are growing angrier and much more willing to use something other than nonviolent, rational discussion to settle disputes and to relieve inner anxieties, frustration, and tensions caused by a broad range of social and economic pressures. Punishment alone has failed to solve the problem, and we have reason to believe that public health strategies may be more effective."

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Animal bite *(continued)*

cubation period and there is a vaccine available to them. Other immunized animals for which a rabies vaccine is available, specifically cows, ferrets, horses, and sheep, would follow observation recommendations.

For all other animals excepts rodents and lagomorphs (i.e., rabbits and hares) the OSDH recommends immediate euthanization and testing. If the biting animal is a stray of unknown immunity status or escapes before it can be captured, the post-exposure prophylactics are recommended as if the animal were infected.

When the euthanization and testing of an animal is necessary, the animal's head should be removed by a veterinarian, packed in cold packs (not wet ice) and sent by courier to the OSDH, which has the only qualified laboratory in the state for such testing.

The Oklahoma State department of Health asks physicians not to hesitate to contact their local health department for assistance with an animal bite situation.

Letters

Former OSMA executive remembers Mark Johnson and his editorials

To the Editor: I was saddened to read this week of the death of Mark R. Johnson, MD. I had the opportunity to work with Dr. Johnson at the Oklahoma State Medical Association from 1975 to 1981. I served as business manager of the JOURNAL and as news editor.

Like most subscribers to the JOURNAL, I always looked forward to reading Dr. Johnson's monthly editorials. Sometimes they made you laugh. Sometimes they made you cry. Sometimes they made you angry. They always made you think.

Not everyone agreed with Mark, and more than once we had our differences. But I feel better off having known him. Mark always had a twinkle in his eye and a zest for what he was doing.

—Richard L. Hess, CAE
OSMA Associate Executive Director, 1975-81

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In Memoriam

1992

Benjamin Joe Myers, MD	May 13
Robert Victor Bolene, MD	May 18
William Anders Crockett, MD	May 30
Charles Jackson Young, MD	May 31
Robert R. Dugan, MD	June 18
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28

1993

Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd Bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
William Niebuhr Weaver, MD	March 20
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Chester Randall Seba, MD	April 4
Edward Cotter Murray, MD	April 9
Eric McLain White, MD	April 23
John Franklin DeJarnette, Jr., MD	May 1
Harold Alwin Smith, MD	May 4
Kenneth Warren Bonham, MD	May 28
John Raymond Stacy, MD	July 6
Carl Davis Osborn, MD	July 11
Mark Royal Johnson, MD	July 12
W. Turner Bynum, MD	July 13

Study suggests abuse, depression as causes of obesity

Obese patients have an unexpectedly high prevalence of previous sexual abuse, chronic depression, and dysfunctional family life, according to Vincent J. Felitti, MD, in the July 1993 issue of *Southern Medical Journal.* Dr. Felitti reports that a study of 12,000 patients in a very low calorie diet program for obese participants, some unexpected behavioral patterns were observed, including (1) dropping the program in the midst of success and (2) rapidly regaining weight loss, at rates distinctly exceeding credible metabolic explanation. Investigation showed a large number of patients exhibiting such behavior were found to have been sexually or otherwise abused during childhood and experience a dysfunctional family life whether as a child or adult.

An additional case control study provided interesting findings, including: (1) Loss of a natural parent in adolescence or before was present in 48% of the obese group compared to 23% of the control group; (2) Alcoholism in at least one parent was present in 40% of the obese, vs. 17% of the controls; (3) Significant degrees of gross current family dysfunction were found in 54% of the obese vs. 16% of the controls; (4) Prolonged or recurrent depression was acknowledged by 57% of the obese vs. 22% of the controls; (5) Chronic sleep disturbance was present in 46% of the obese, 23% of the controls.

The author suggests that to obtain a true medical history of an obese patient, the physician should include questions on depression, physical or sexual abuse, and participation in a dysfunctional family.

Copies of the article may be obtained by faxing a request to Kathy McLendon, (205) 942-0642.

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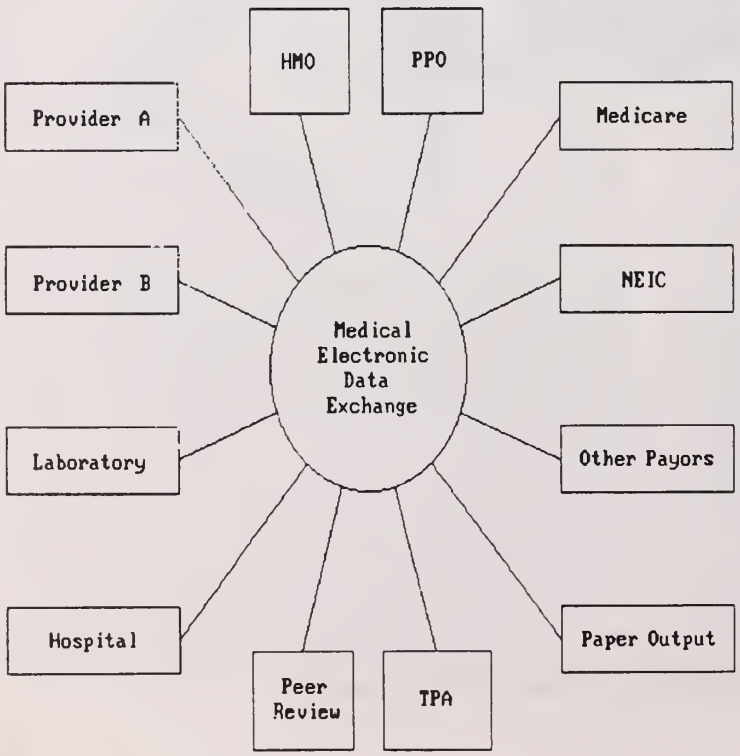
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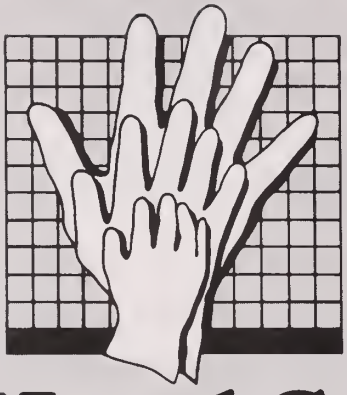
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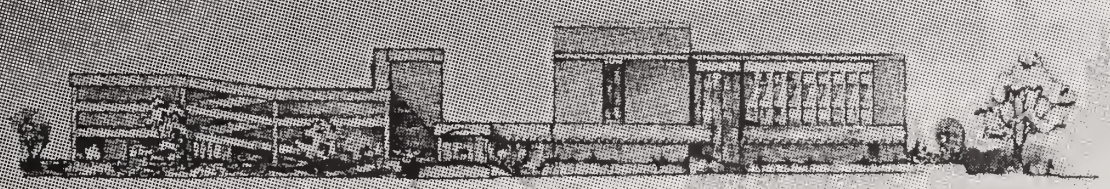
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All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style*. An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

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Together Everyone Achieves More

Auxiliary members are off to an enthusiastic start for the year. We have just finished the "Pony Express," which took the membership team from the state to different counties. We were greeted with an excellent response. The team consisted of our Membership Chair, AMA-ERF Chair, Health Promotion Chair, and the President and President-Elect. We found sharing programs and ideas with the counties beneficial to everyone involved.

The theme of "Together Everyone Achieves More" is appropriate in every area we share as auxilians and spouses of physicians. Physicians and their families continue to undergo stress from the community and the government. We find continuing stress coming from negative opinion polls of doctors in America, and from the fear that changes made in health care will be useless, and not target areas that need reform.

Legislative affairs will continue to be an area of great concern to auxilians. Members are being encouraged to become a part of the campaigns of their local, state, and national legislators. Only through this personal involvement can we have any impact in the legislative area today. The changes occurring in medicine are more significant than ever before. As we see physicians trying to preserve a future autonomy, we must realize that our legislative input is more essential than ever before. We must speak with one voice in the medical community.

This year the OSMA has asked auxilians to serve on every OSMA council. We will work with the OSMA on dispersing legislative information, and in developing a legislative program day for both physicians and spouses.

This year the OSMAA will emphasize the prevention of family violence, child abuse, and safety with children through our Health Promotion Committee. We have resources available to the counties that consist of videos, information pamphlets, and books that are dedicated to these areas. We also are available to suggest speakers to go with these programs.

AMA-ERF continues to be the emphasis of the only joint fundraiser that we do with the AMA Alliance and the AMA. Last year the University of Oklahoma received the sixth largest amount of funds to be given to medical schools throughout the United States. As you can see, we are making a difference in Oklahoma. This year nearly 2.5 million dollars for medical education and research was raised in the United States, and we hope to increase Oklahoma's donations for the 1993-94 year. This year's theme is "One Choice—One Hour." If each auxilian will contribute at least one hour of medical education, that alone will increase contributions in the state. "One Choice—One Hour" means contributing $21.03 to AMA-ERF—every member buys one hour of medical education for one medical student.

This year Oklahoma auxilians again won a membership award. We continue to stress membership as the key to making our program successful throughout the state. This year we will work on our "One Choice—One Plus" Membership Program to add active members, members-at-large, or resident/medical student spouses to our auxiliary. We need all physicians to encourage their spouses to join the auxiliary.

We continue to face the future as a TEAM in auxiliary. We have renewed our commitment to work together as friends, spouses, and community members to accomplish desired changes in both our local communities and the future of a new medical environment. Please join with us in Auxiliary. We need each one of you!

—Karen Mask
OSMAA President

THE LAST WORD

■ **The AMA is encouraging physicians to express** their health care system views by writing editorials for local newspapers. Physicians can greatly influence public opinion and be responsive to patients' needs by writing about how to evaluate the President's proposal. A sample editorial has been written and is available on the AMA's electronic network. It may be downloaded as either WordPerfect or ASCII text. The file names are Bull724.WP and Bull724.ASC, respectively.

■ **Only six PLICO-sponsored loss prevention seminars** remain in 1993, according the August *OSMA News*. Physicians who last attended a loss prevention seminar in 1990 must attend another this year in order to remain eligible for their PLICO liability coverage. Also, new physicians are required to attend such a seminar during their first full year after obtaining PLICO coverage. Physicians unsure about whether they must attend this year may call Debbie Thurmond at OSMA headquarters, 1-800-522-9452 or (405) 843-9571 for information. The dates of the remaining seminars, all in either Tulsa or Oklahoma City, are September 24 and 26, October 5, 7, and 16, and November 7.

■ **Ray V. McIntyre, MD, Kingfisher, has been** named Oklahoma's Family Doctor of the Year by the Oklahoma Academy of Family Physicians. Dr. McIntyre recently retired after some 40 years of practice in Kingfisher, has been a staunch advocate of state child laws as well as the establishment of an office overseeing the state's child abuse examiner program.

■ **AMA President Joseph T. Painter, MD, has announced** plans for three regional AMA-sponsored meetings entitled "Physician Forum: Agenda for Action." The goal of the meetings will be to expand two-way communications between the AMA leadership and grass roots physicians. Clinton administration officials, members of Congress, and other key players in health system reform will take part in each meeting. Dates and locations are October 23, San Francisco; November 5, Dallas; and November 20, Philadelphia. For additional information and registration information, call 1-800-621-8335.

■ ***The Wall Street Journal* has featured the AMA's** "10 questions" leaflet, called "Is the Clinton Proposal for Health Reform Good for You and Your Family?" According to the newspaper, the leaflet "is popping up in doctors' offices across the U.S." For copies of the leaflet, call 1-800-348-3047 and ask for Department 25.

■ **The AMA, in cooperation with the Medical Association** of Georgia and the Florida Medical Association, will host the fourth annual Interactions Medical Staff Leadership Conference in Naples, Florida, October 1-3. The three-day conference, called "Managing Change," is an effort to educate and develop physician leadership and is designed for both new and experienced medical staff leaders. For additional information or to register, call 1-800-621-8335.

■ **John I. Fishburne, Jr., MD, James A. Merrill** Chair and professor and chairman of the Department of Obstetrics and Gynecology at the University of Oklahoma, has been named chair of the Residency Review Committee for Obstetrics and Gynecology by the American Council on Graduate Medical Education.

■ **The International Conference on Physician** Health, to be held September 14-18, 1994, in Ottawa, Ontario, Canada, is accepting abstracts addressing topics related to physician health, including AIDS, HIV, problems related to aging, mental illness, substance abuse, and physical disabilities and limitations, including those caused by general medical conditions. Possible topics for presentation include: presentation and treatment of health problems among physicians, the impact of disorders on physicians' families and practices, medical-legal issues facing hospital administrations and licensing boards, and material on health promotion and disease prevention. Abstracts which address issues related to these topics (i.e., prevention, diagnosis, treatment, rehabilitation), but not dealing specifically with physicians also are welcome. Submission deadline: February 1, 1994. Contact Elaine M. Tejcek, Department of Mental Health, American Medical Association, 515 North State Street, Chicago, IL 60610, (312) 464-5073.

leference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-esponse study. *Clin Cardiol.* 1991;14:146-151.

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Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in some patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 6 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, clofibric acid, or probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*; a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated, adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below, also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions. An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Issued March 1993

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THE PRAVACHOL® DIRECTION IN LIPID MANAGEMENT

Effective lipid management doesn't have to be tough



- Improves key lipids — significant reduction in LDL-C[1]
- Excellent safety profile
- Easy for patients — once-daily dosing, well tolerated
- Usual dose: 20 mg once daily at bedtime, with or without food

PRAVACHOL pravastatin sodium 20 m tabl

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PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels i patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

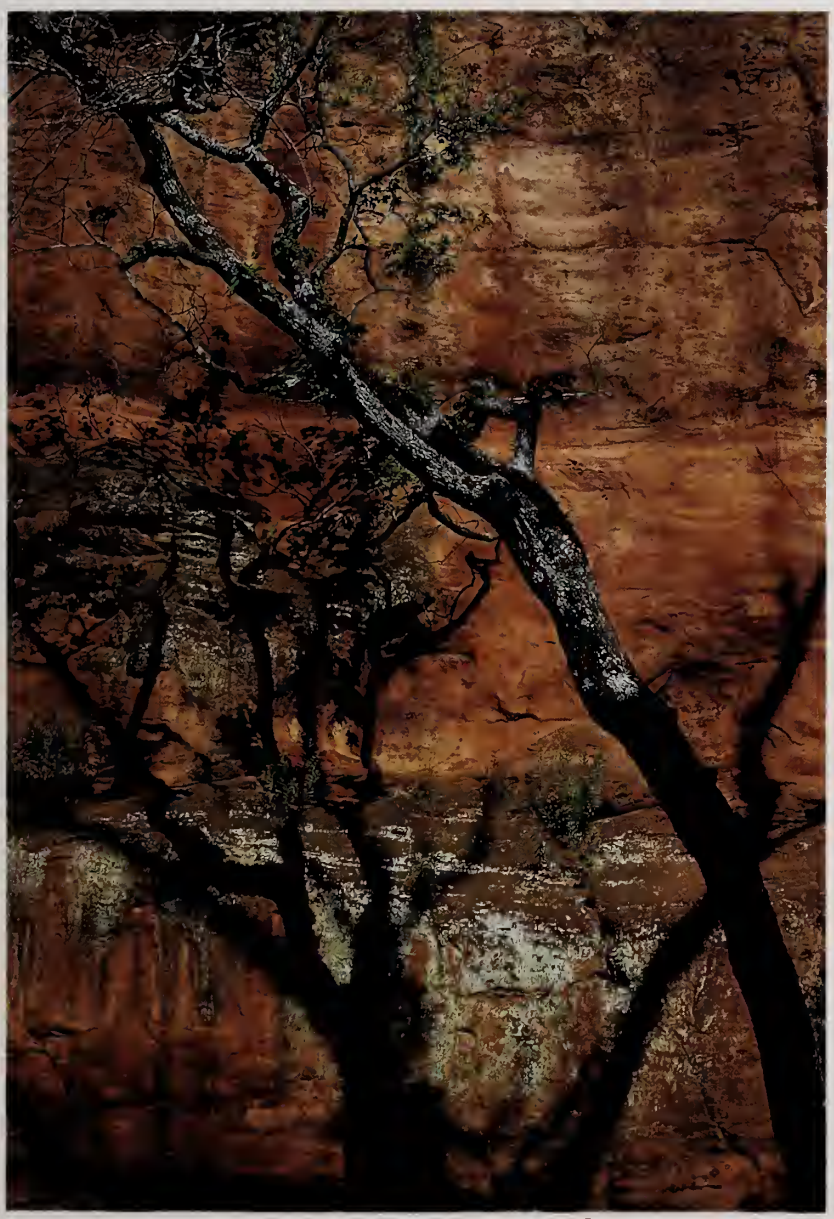
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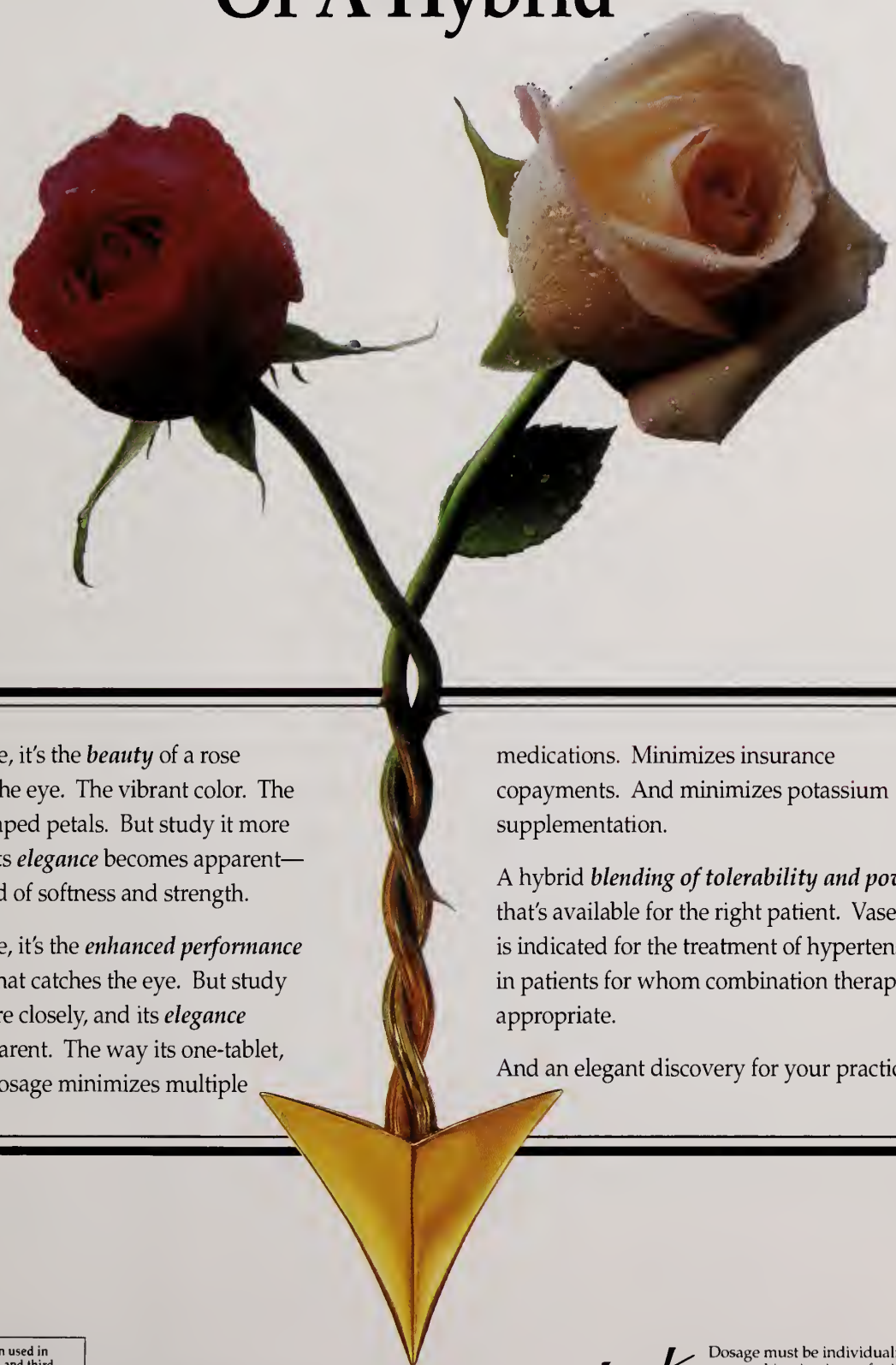
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At first glance, it's the ***beauty*** of a rose that catches the eye. The vibrant color. The delicately shaped petals. But study it more closely, and its ***elegance*** becomes apparent—a gentle blend of softness and strength.

At first glance, it's the ***enhanced performance*** of Vaseretic that catches the eye. But study Vaseretic more closely, and its ***elegance*** becomes apparent. The way its one-tablet, once-a-day dosage minimizes multiple medications. Minimizes insurance copayments. And minimizes potassium supplementation.

A hybrid ***blending of tolerability and power*** that's available for the right patient. Vaseretic is indicated for the treatment of hypertension in patients for whom combination therapy is appropriate.

And an elegant discovery for your practice.

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Vaseretic® (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*

VASERETIC® 10-25 *Next*
Enalapril Maleate-Hydrochlorothiazide

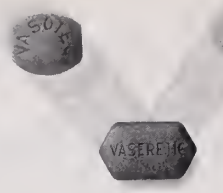
Dosage must be individualized; the fixed combination is not for initial therapy.

Evaluation of the hypertensive patient should always include assessment of renal function.

For a Brief Summary of Prescribing Information, see adjacent pages.

TABLETS
VASERETIC®
(ENALAPRIL MALEATE-HYDROCHLOROTHIAZIDE)

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC (Enalapril Maleate-Hydrochlorothiazide) should be discontinued as soon as possible. See WARNINGS, *Fetal/Neonatal Morbidity and Mortality.*



10 mg 25 mg

CONTRAINDICATIONS: VASERETIC is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor. Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

WARNINGS: *General; Enalapril Maleate; Hypotension:* Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of enalapril use in severely salt/volume depleted persons such as those treated vigorously with diuretics or patients on dialysis.

Syncope has been reported in 1.3 percent of patients receiving VASERETIC. In patients receiving enalapril alone, the incidence of syncope is 0.5 percent. The overall incidence of syncope may be reduced by proper titration of the individual components. (See PRECAUTIONS, *Drug Interactions*, and ADVERSE REACTIONS.)

In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of enalapril and/or diuretic is increased. Similar considerations may apply to patients with ischemic heart or cerebrovascular disease, in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in the supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses, which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including enalapril. In such cases VASERETIC should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway, should be promptly provided.** (See ADVERSE REACTIONS.)

Patients with a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema while receiving an ACE inhibitor (see also CONTRAINDICATIONS).

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of enalapril are insufficient to show that enalapril does not cause agranulocytosis at similar rates. Marketing experience has revealed several cases of neutropenia or agranulocytosis in which a causal relationship to enalapril cannot he excluded Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects of the drug may develop in patients with impaired renal function.

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Lithium generally should not be given with thiazides (see PRECAUTIONS, *Drug Interactions, Enalapril Maleate and Hydrochlorothiazide).*

Pregnancy, Enalapril-Hydrochlorothiazide: There was no teratogenicity in rats given up to 90 mg/kg/day of enalapril (150 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose) or in mice given up to 30 mg/kg/day of enalapril (50 times the maximum human dose) in combination with 10 mg/kg/day of hydrochlorothiazide (2 ½ times the maximum human dose). At these doses, fetotoxicity expressed as a decrease in average fetal weight occurred in both species. No fetotoxicity occurred at lower doses; 30/10 mg/kg/day of enalapnl-hydrochlorothiazide in rats and 10/10 mg/kg/day of enalapnl-hydrochlorothiazide in mice.

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, VASERETIC should be discontinued as soon as possible. (See *Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality,* below.)

Enalapril Maleate; Fetal/Neonatal Morbidity and Mortality: ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, ACE inhibitors should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of VASERETIC as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

If oligohydramnios is observed, VASERETIC should he discontinued unless it is considered lifesaving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of *in utero* exposure to ACE inhibitors should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should he directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may he required as means of reversing hypotension and/or substituting for disordered renal function. Enalapnl, which crosses the placenta, has been removed from neonatal circulation by pentoneal dialysis with some clinical benefit, and theoretically may be removed hy exchange transfusion, although there is no experience with the latter procedure.

No teratogenic effects of enalapril were seen in studies of pregnant rats, and rabbits. On a mg/kg basis, the doses used were up to 333 times (in rats), and 50 times (in rabbits) the maximum recommended human dose.

Hydrochlorothiazide; Teratogenic Effects: Reproduction studies in the rabbit, the mouse and the rat at doses up to 100 mg/kg/day (50 times the human dose) showed no evidence of external abnormalities of the fetus due to hydrochlorothiazide. Hydrochlorothiazide given in a two-litter study in rats at doses of 4 - 5. 6 mg/kg/day (approximately 1 - 2 times the usual daily human dose) did not impair fertility or produce birth abnormalities in the offspnng. Thiazides cross the placental barrier and appear in cord blood.

Nonteratogenic Effects. These may include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

PRECAUTIONS: *General; Enalapril Maleate: Impaired Renal Function:* As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including enalapril, may be associated with oliguna and/or progressive azotemia and rarely with acute renal failure and/or death.

In clinical studies in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine were observed in 20 percent of patients. These increases were almost always reversible upon discontinuation of enalapnl and/or diuretic therapy. In such patients renal function should be monitored during the first few weeks of therapy.

Some patients with hypertension or heart failure with no apparent preexisting renal vascular disease have developed increases in blood urea and serum creatinine, usually minor and transient, especially when enalapnl has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of enalapril and/or discontinuation of the diuretic may he required.

Evaluation of the hypertensive patient should always include assessment of renal function.

Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes (e.g., AN 69*) and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to using a different type of dialysis membrane or a different class of antihypertensive agent.

Hyperkalemia: Elevated serum potassium (greater than 5.7 mEq/L) was observed in approximately one percent of hypertensive patients in clinical trials treated with enalapril alone. In most cases these were isolated values which resolved despite continued therapy, although hyperkalemia was a cause of discontinuation of therapy in 0.28 percent of hypertensive patients. Hyperkalemia was less frequent (approximately 0.1 percent) in patients treated with enalapril plus hydrochlorothiazide. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-spanng diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with enalapril. (See *Drug Interactions.*)

Cough: Cough has been reported with the use of ACE inhibitors Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, enalapril may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Hydrochlorothiazide: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Warning signs or symptoms of fluid and electrolyte imbalance, irrespective of cause, include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, seizures, muscle pains or cramps, muscular fatigue, hypotension, oliguna, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or after prolonged therapy. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia may cause cardiac arrhythmia and may also sensitize or exaggerate the response of the heart to the toxic effects of digitalis (e.g., increased ventricular irritability). Because enalapril reduces the production of aldosterone, concomitant therapy with enalapril attenuates the diuretic-induced potassium loss (see *Drug Interactions, Agents Increasing Serum Potassium).*

Although any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease), chloride replacement may be required in the treatment of metabolic alkalosis.

Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropnate replacement is the therapy of choice.

Hyperuncemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

In diabetic patients dosage adjustments of insulin or oral hypoglycemic agents may be required. Hyperglycemia may occur with thiazide diuretics. Thus latent diabetes mellitus may become manifest during thiazide therapy.

The antihypertensive effects of the drug may be enhanced in the postsympathectomy patient.

If progressive renal impairment becomes evident consider withholding or discontinuing diuretic therapy.

Thiazides have been shown to increase the urinary excretion of magnesium; this may result in hypomagnesemia.

Thiazides may decrease urinary calcium excretion. Thiazides may cause intermittent and slight elevation of serum calcium in the absence of known disorders of calcium metabolism. Marked hypercalcemia may be evidence of hidden hyperparathyroidism. Thiazides should be discontinued before carrying out tests for parathyroid function.

Increases in cholesterol and triglycende levels may be associated with thiazide diuretic therapy.

Information for Patients; Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of enalapril. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patients should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with the physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (e.g., sore throat, fever) which may be a sign of neutropenia.

Pregnancy: Female patients of childbearing age should be told about the consequences of second- and third-trimester exposure to ACE inhibitors, and they should also be told that these consequences do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. These patients should be asked to report pregnancies to their physicians as soon as possible.

NOTE: As with many other drugs, certain advice to patients being treated with VASERETIC is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

Drug Interactions; Enalapril Maleate; Hypotension—Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with enalapril. The possibility of hypotensive effects with enalapril can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with enalapril. If it is necessary to continue the diuretic, provide medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS.)

Agents Causing Renin Release: The antihypertensive effect of enalapril is augmented by antihypertensive agents that cause renin release (e.g., diuretics).

Other Cardiovascular Agents: Enalapril has been used concomitantly with heta adrenergic-blocking agents, methyldopa, nitrates, calcium-blocking agents, hydralazine and prazosin without evidence of clinically significant adverse interactions.

Agents Increasing Serum Potassium: Enalapril attenuates diuretic-induced potassium loss. Potassium-sparing diuretics (e.g., spironolactone, triamterene, or amilonde), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia they should be used with caution and with frequent monitonng of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium concomitantly with drugs which cause elimination of sodium, including ACE inhibitors. A few cases of lithium toxicity have been reported in patients receiving concomitant enalapnl and lithium and were reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if enalapnl is administered concomitantly with lithium

Hydrochlorothiazide; When administered concurrently the following drugs may interact with thiazide diuretics.

Alcohol, barbiturates, or narcotics—potentiation of orthostatic hypotension may occur.

Antidiabetic drugs (oral agents and insulin)—dosage adjustment of the antidiabetic drug may be required.

Other antihypertensive drugs—additive effect or potentiation.

Cholestyramine and colestipol resins—Absorption of hydrochlorothiazide impaired in the presence of anionic exchange resins. Single doses of either cholestyramine or colestipol resins bind the hydrochlorothiazide and reduce its absorption from the gastrointestinal tract hy up to 85 and 43 percent respectively.

Corticosteroids, ACTH—intensified electrolyte depletion, particularly hypokalemia.

Pressor amines (e.g., norepinephrine)—possihle decreased response to pressor amines but not sufficient to preclude their use.

Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)—possible increased responsiveness to the muscle relaxant.

Lithium—should not generally be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high nsk of lithium toxicity. Refer to the package insert for lithium preparations before use of such preparations with VASERETIC.

Non-steroidal Anti-inflammatory Drugs—In some patients, the administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic and antihypertensive effects of loop, potassium-sparing and thiazide diuretics. Therefore, when VASERETIC and non-steroidal anti-inflammatory agents are used concomitantly, the patient should be observed closely to determine if the desired effect of the diuretic is obtained.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Enalapril in combination with hydrochlorothiazide was not mutagenic in the Ames microbial mutagen test with or without metabolic actuation. Enalapril-hydrochlorothiazide did not produce DNA single strand breaks in an *in vitro* alkaline elution assay in rat hepatocytes or chromosomal aberrations in an *in vivo* m

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bone marrow assay.

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity.

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/ml, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings, Serum Electrolytes: See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen: In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests: Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported: *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest, myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction, pulmonary edema, rhythm disturbances including atrial tachycardia and bradycardia; atrial fibrillation, hypotension, angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported; a causal relationship to enalapril has not been established; *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, pemphigus, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—*Body as a Whole:* Weakness; *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia; *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness; *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg.

For more detailed information, consult your DuPont Pharma Representative or see Prescribing Information.

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YOCON®
YOHIMBINE HCl

Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalmic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon* is indicated as a sympathicolytic and mydriatic. It may have activity as an aphrodisiac.

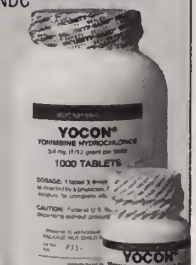
Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.[1,2] Also dizziness, headache, skin flushing reported when used orally.[1,3]

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.[1,3,4] 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to ½ tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.[3]

How Supplied: Oral tablets of Yocon* 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.



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JOURNAL

OKLAHOMA STATE MEDICAL ASSOCIATION

OCTOBER 1993 VOL. 86, NO. 10

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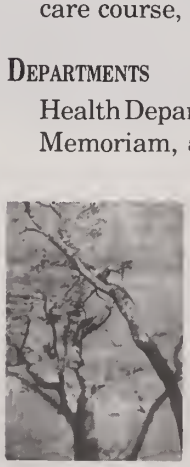
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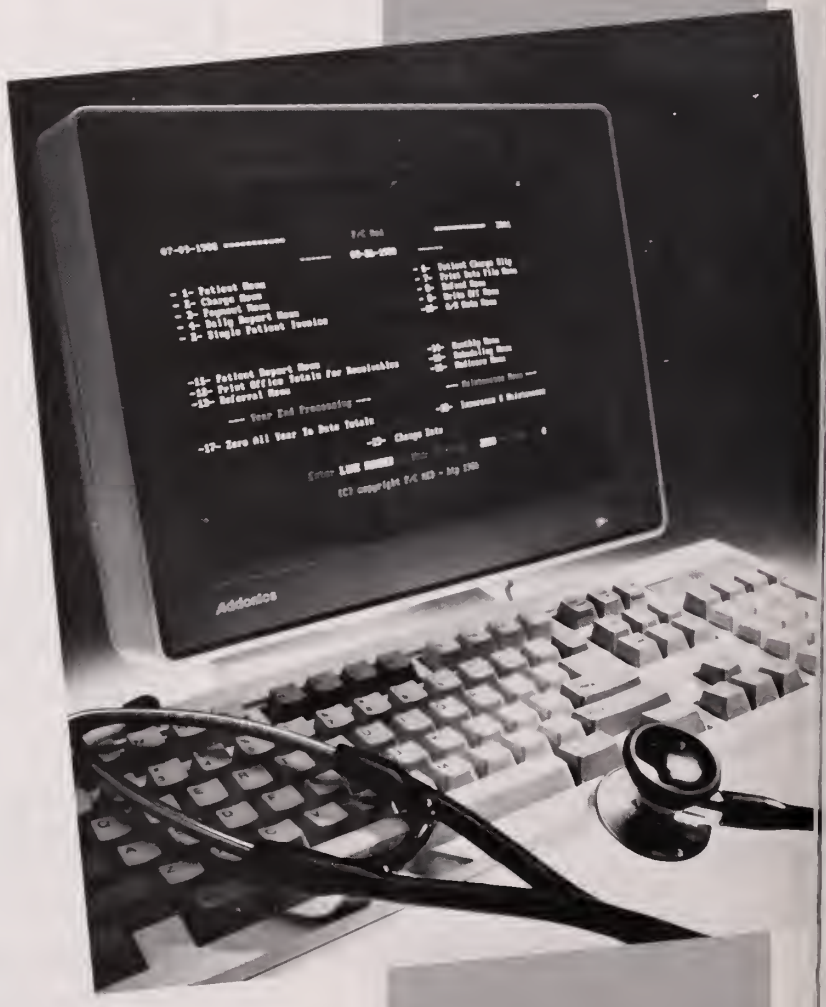
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Ray V. McIntyre, MD

Poor, Poorer, Poorest

Increasingly, published reports state that morbidity and mortality rates are correlated to economic class. America's lower economic class is sicker oftener and longer and dies sooner than the upper economic class. As statistical studies are refined and outcome audits multiply, this traditional suspicion comes closer to scientific certainty.

This is a disturbing trend, as many visionaries hope to make our culture a classless society where the rich are not rewarded for their wealth nor the poor punished by their poverty.

But the moral concept of reward and punishment should not be connected to the etiology of health and disease. The gonococcus cannot distinguish a faithful from an unfaithful urethra. Cancer kills as many saints as sinners. Disease and death are not punishments for immoral behavior, but rather consequences of the interaction of human physiology with time and an inconstant environment. It seems reasonable to derive the idea that stressful adaption difficulties predisposing to disease are more frequent among those with the least financial resources.

When we consider the details of the methods by which cancer or the gonococcus select their victims, or violent death and disability are inflicted on humans, we can reasonably conclude that decreasing resources progressively increase exposure to human illness. The prevalence of morbidity consequent to substance abuse is increased in those of limited resources. There are also significant differences in urban/rural medical results, with effects on maternity care and trauma. Geography and distance create a dimension separate from economic class, and the rural effect relates to access to care and facilities.

The more sophisticated we become in plumbing the etiology of disease, the more it seems that disease and injury causation falls outside the powers of the physician. we use vaccines, chemotherapy, and antibiotics in a tactical battle after a strategic defeat. The bullets and bombs fly irrespective of physician cleverness in repairing trauma damage. The more we learn about cancer, the more important become heredity and nutrition and nicotine addiction.

Thus the physician can justly deduce that although the poor are sicker and die sooner, medical science is "not guilty." Physicians do extremely well in unraveling the tangled skein of diagnosis and treatment of human illness and injury, and are successfully applying expert knowledge to most of the patients in every economic group.

Blame, if it must be assessed, may be aimed at the world's politicians and war lords that so much poverty remains in the modern world. But we remember that *poor* is a comparative adjective, and when applied to resources is always a relative term. When we use the word *poor,* it must be re-defined for every time and place, and for every nation, culture, and human epoch. It has been wisely and truly said: "..the poor always ye have with you."

Ray V. McIntyre, M.D.

My Daddy's a Doctor...

Practicing medicine should never be disappointing, but it can be— *to you, your family and even your patients* —when you need more than 24 hours a day to get everything done. Keeping up with medical advancements and professional reading already takes most of your free time. Don't let paperwork and personnel emergencies consume the rest.

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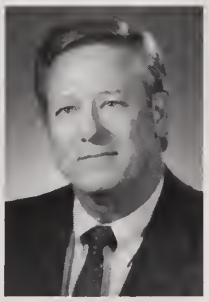
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G. Lance Miller, MD

Doctor Beware



As human beings, doctors are prey to the malady of taking important things for granted. Seldom do I hear my peers discuss the incredible advantage they hold over physicians outside our state. I am referring to the fact that our association-sponsored malpractice insurance company provides Oklahoma physicians with the lowest priced insurance available and is the only company still providing occurrence-type coverage. Unfortunately, taking this unique situation for granted has worked to the detriment of a number of physicians in our association over the past few years.

The Oklahoma State Medical Association has long been at the forefront in providing its members with top-rated insurance, as evidenced by its position in 1948 as the first state medical association to sponsor a malpractice insurance program. For several decades thereafter, medical malpractice premiums remained quite reasonable because the litigious disease in our society had not yet been spawned.

By the mid-seventies, however, insurance premiums had skyrocketed, and most national insurance companies had gotten out of the malpractice insurance business or had begun the irreversible shift toward providing only claims-made coverage.

Prompted by these events, the OSMA Board of Trustees decided to take the plunge and in 1979 created PLICO to guarantee our physicians would maintain control of their own financial destiny. A major factor in the decision to form PLICO was the Board of Trustees' confidence that unity within the Oklahoma State Medical Association was sufficient to guarantee the level of participation needed to support the company.

The philosophy adopted by the PLICO board upon its creation was based on the following principles:

1. Never pay one penny for tribute.
2. Keep the price for insurance as low as possible.
3. Meet the needs of all physicians by maintaining a flexible and fair policy.
4. Guarantee the coverage cannot be terminated without a fair judgment of the individual's peers.
5. Handle claims in a way that provides the best protection for the physician, and see that the physician retains the ultimate right to decide whether a claim should be settled or litigated.
6. Provide a policy that will protect the physician in all medically related activities, and make every effort to continue occurrence-type coverage.
7. Institute no discrimination in price based on the location of the physician's practice within the state.
8. Ensure that the company will always be owned by physicians through the OSMA and that only physicians will run it.

During the first six years of its existence, PLICO provided premium savings to Oklahoma physicians in excess of $9 million. During the same period, premiums in surrounding states doubled or tripled. Since 1979, PLICO has saved Oklahoma physicians over $300 million.

The success of PLICO has been dependent on a number of factors, but the most important of these has been the unity demonstrated by association members throughout the years.

I suspect that many physicians do not understand the importance of occurrence coverage as compared to claims-made coverage. It is, I feel, critical that physicians understand the difference, considering the myriad changes occurring in the current medical environment.

There are many hidden expenses in claims-made coverage that are not at all obvious until one has studied insurance. The general premise of this type of coverage is that premiums will be relatively low in the early years of coverage, but will continue to escalate for a long time into the coverage. The most critical difference, however, lies in the fact that claims-made coverage ceases at the end of each year and must be renewed. This requires the physician to purchase a long "tail" of coverage after retiring from practice. This expense occurs at a time when most of us will be attempting to reduce ongoing expenses and can be a very difficult issue to manage. Yet without this tail coverage, a non-practicing physician can be exposed to extreme financial burdens resulting from care rendered years earlier.

I bring this issue to your attention at this time because a significant number of association members

are selling their practices to hospitals or other corporate entities and thus are becoming employees of those entities. I feel it is my duty to warn all physicians who contemplate such a career move to seriously consider the insurance implications of that move. I urge these physicians to be alert to the need to negotiate into their contract of sale a clause that compels the purchasing entity to continue their PLICO insurance for them.

Consider the following:

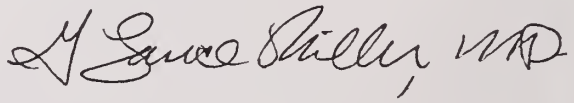
1. If the physician is terminated by the employer, occurrence-type insurance coverage will be needed to ensure the physician will not be out the expense of purchasing tail insurance or have a gap in coverage.
2. To remain able to negotiate as a free agent, the physician needs occurrence coverage and should not have to depend upon the self-insurance of an employer for protection.
3. If the physician is insured by the employer's insurer, or an insurance plan controlled by the employer, the employer may dump all of the losses on the physician and the national data bank will record them. Physicians need to control their own defense, and only with PLICO can they do that.
4. If the employer suffers financial difficulty, goes out of business, or is sold, the physician could be left without any coverage at all for losses incurred during employment by that entity. Of course, if the physician has been covered by PLICO's occurrence coverage, there would be no problem.

Considering the changes that are taking place and the competitive market for medical services, physicians could get caught in any of these situations if they do not maintain their own independent insurance policy for professional liability. The least of the physician's worries becomes the inability to negotiate if another employer makes a better offer. The biggest of the physician's worries is long-term financial security, his or her children's education, and retirement—all of which could be threatened.

PLICO's occurrence coverage is the Cadillac of medical malpractice insurance available on the market today and is the only coverage that provides the security each of us deserves.

For obvious reasons, it also would be advantageous for all physicians considering the sale of their practice to make every attempt to keep their PLICO health insurance. Physicians will not find elsewhere the advantages of guaranteed insurability and reinsurability based on the fact that they are physicians.

Doctor, beware!



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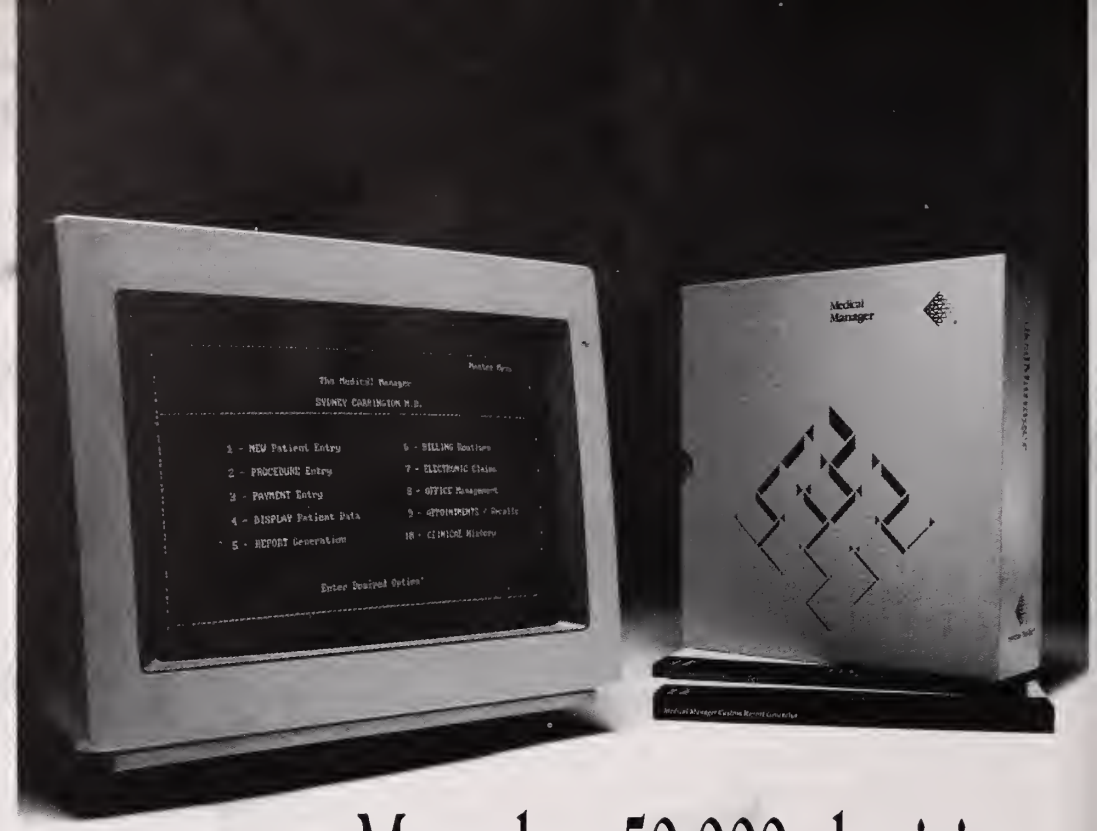
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Laparoscopic Assisted Vaginal Hysterectomy: A Report of 26 Cases

Royice B. Everett, MD

This study was undertaken to evaluate the feasibility and safety of laparoscopic assisted vaginal hysterectomy. We have retrospectively studied the first twenty-six cases. All cases were reviewed and included in this report. The complication rate is very minimal and well below that which would be expected from abdominal or vaginal hysterectomy approach. The operative time is approximately double that of a standard approach; however, the hospital stay is greatly decreased and the patient's return to normal activity has been considerably shortened when compared to the standard abdominal procedure. We conclude that the operation is not only feasible, but should be considered any time an abdominal approach to hysterectomy is being contemplated.

HYSTERECTOMY IS THE MOST COMMONLY PERFORMED gynecologic procedure in the United States today. There are an average of 700,000 hysterectomies performed each year. This number is likely to increase over the next ten to fifteen years as the baby boom generation, born between 1946 and 1960, will be reaching the age most commonly associated with hysterectomy.

Approximately 75% of the hysterectomies performed in the United States are performed abdominally.[1] In 1989 Reich and DeCaprio reported the first laparoscopic hysterectomy using aqua-dissection and bipolar cautery for hemostasis and dissection.[2] Since that time, the term *laparoscopic assisted vaginal hysterectomy* has been used extensively. Reich and DeCaprio in their initial report differentiated between laparoscopic assisted hysterectomy as those in which the vascular pedicles are divided laparoscopically, and laparoscopic assisted vaginal hysterectomy, in which uterine vasculature was ligated vaginally. Several variations on this theme have been developed over the last two years.

The purpose of this report is to describe our first twenty-six patients. This report includes all patients from the first procedure done in April 1991 through September 1992. Our intent is to show that laparoscopic assisted hysterectomy can be performed safely with minimal morbidity and establish the validity of replacing the traditional abdominal hysterectomy, at least for benign lesions, with the laparoscopic approach.

It is clear that there are major patient benefits associated with this surgery by avoiding laparotomy. These include reduced surgical risk, reduced recovery times, and reduced pain, resulting in quicker return to normal activities and decreased morbidity. Gynecologists have long appreciated the benefits of vaginal surgery over abdominal surgery with respect to recovery time and postoperative morbidity and discomfort. The major benefit of the laparoscopic assisted procedures is converting previous abdominal surgery to a laparoscopic assisted vaginal approach. Indications include pelvic pain with suspicion of intra-abdominal pathology such as endometriosis, adhesions, or ovarian enlargement. Vaginal stenosis and lack of descensus of the uterus may also eliminate the traditional vaginal approach. Other indications would be concomitant surgery such as indicated appendectomy.

From Baptist Medical Center of Oklahoma, Oklahoma City.
Direct correspondence to Royice B. Everett, MD, 3433 Northwest 56th, Suite 870, Oklahoma City, OK 73112.

Materials and Methods

During the period April 1991 to September 1992, twenty-six women underwent laparoscopic assisted vaginal hysterectomy using three different techniques. These will be described separately. The ages ranged from 30 to 72 years. Indications for the surgery are the same as for abdominal hysterectomy and are tabulated in Table 1. Previous abdominal surgery had been performed in twenty patients.

Preoperative consultation included total explanation of the procedure as well as risks and benefits and also the possibility that an open operation might be necessary if the procedure could not be completed through the laparoscope. All operations were performed under general anesthesia with endotracheal intubation. Patients were placed in steep Trendelenburg position with both legs supported in Allen stirrups (Allen Medical, Mayfield, Ohio). The bladder was drained prior to surgery, and the anesthesiologist administered indigocarmine intravenously following the induction of anesthesia. The Valchev™ uterine manipulator was used in all cases. A ten-millimeter diagnostic laparoscope was used interchangeably with an eleven-millimeter CO_2 laser laparoscope through a disposable twelve-millimeter trocar inserted through the base of the umbilicus.

All procedures were performed via video transmission with two color monitors. Operative technique and trocar placement varied somewhat throughout the cases. The last several procedures have been done through two five-millimeter lateral ports placed in the lower pelvis lateral to the epigastric vessels as well as a central twelve-millimeter port inserted approximately five centimeters above the two lateral ports in the midline. Some variation in the puncture sites was allowed secondary to pelvic pathology including uterine size and or leiomyomata and adnexal enlargement.

Table 1. Indications for Hysterectomy

Indications	No. of Patients
Adhesions	12
Pelvic pain	15
Hypermenorrhea	13
Enlarged fundus	5
Adenocarcinoma	1
Endometriosis	4
S.U.I.	2
Total	52

Some patients had more than one diagnosis

AFTER THE INSERTION OF ALL TROCAR PORTS, INspection of the intra-abdominal cavity was carried out and all preliminary procedures were performed. Preliminary procedures included dissection of endometriosis, lyses of adhesions, and inspection of the upper abdominal cavity. During this part of the procedure, except for the upper abdominal exploration, the patient is placed in fifteen- to twenty-degree Trendelenburg position, allowing all of the intra-abdominal organs to fall away from the pelvic floor. A suction irrigator was used during this process for manipulation of the intra-abdominal contents. In cases where intra-abdominal adhesions and endometriosis were encountered, the CO_2 laser was used to dissect the adhesions and for ablation and/or excision of the endometrial implants. Klepinger bipolar forceps also were used for hemostasis in dissection of larger adhesions where blood vessels were encountered prior to cutting with CO_2 laser.

Following completion of the preliminary procedure, the round ligaments were completely desiccated with bipolar cautery and divided with sharp dissection or CO_2 laser if the laser had been in use previously. In patients in whom a unilateral or bilateral salpingo oophorectomy was performed, the infundibulopelvic ligament was isolated and divided using a Multifire Endo GIA 30. The mesosalpinx and uteroovarian ligaments were then excised using Klepinger bipolar forceps for desiccation and sharp dissection down to the uterine fundus and inferiorly to the uterine artery on either side. The bladder flap was then dissected anteriorly with sharp dissection using bipolar cautery for hemostasis or with CO_2 or Nd:YAG laser, which may be used interchangeably depending on the surgeon's choice and experience. All of these methods work quite well. Hemostasis is somewhat better obtained when using laser dissection. The bladder flap is developed down to the distal cervical area.

From this point forward there is some variation in the technique to complete the procedure. Discussion regarding potential benefits and risks of each dissection technique will follow. At this point the procedure can proceed to the vaginal component and be completed with the Dodorlein approach to the remaining part of the hysterectomy. This was done in fifteen of the reported cases. The discussion of the vaginal component of this technique will be continued later.

If the procedure is to be completed as originally described, the next step is to identify the ureter, which can be found just passing under the uterine artery and somewhat laterally.[2] Once this is identified and noted to be away from the area of further coagulation or dis-

Table 2. Postoperative Diagnosis

Adhesions	16
Fundus >120 grams	15
Adenocarcinoma	1
Endometriosis	5
Adenomyosis	4
Total	41

Some patients had more than one diagnosis

section, the uterine artery can either be clamped with an Endo GIA or desiccated with bipolar cautery and/or suture ligated. After the uterine artery is secured on each side, the remaining path of the ureter must be identified before the procedure is completed. If a linear stapling device or electrocautery is to be used below the uterine artery, the ureter must be identified and noted to be away from the area of further dissection and division. The uterosacral and cardinal ligaments may be ligated through the vaginal approach.

The next step is to enter the anterior and posterior vaginal cuff laparoscopically. This can be most easily accomplished by placing a moistened gauze in the anterior cul-de-sac above the cervix, and this should be apparent laparoscopically just below the dissected bladder if the bladder flap has been dissected appropriately. Once the placement of the sponge is identified, the anterior vagina can be opened either with sharp dissection, CO^2 laser, or Nd:YAG laser. The moistened gauze sponge placed in the anterior cul-de-sac vaginally is very helpful in this procedure. The posterior cul-de-sac can be very easily identified when using the Valchev™ uterine manipulator since the metal portion of the back side of the manipulator is easily identified in the posterior cul-de-sac and can be used as a backstop for the CO^2 laser or Nd:YAG laser. Once the cul-de-sac is entered both anteriorly and posteriorly, the vaginal portion of the procedure begins.

The third possible approach from above is a supracervical hysterectomy. This is completed in the same manner as previously discussed until the dissection and coagulation and/or suturing of the uterine arteries is completed. The cervix is then cut across in an inverted cone-shaped fashion, leaving the cervical stump with a small part of the endocervical canal present in the distal part of the cervix. This leaves the uterus, tubes, and ovaries free inside the abdominal cavity. This particular procedure, as described by Lyons,[3] continues by inspection of the vaginal cuff for any bleeding and ablating any of these bleeding sites with either bipolar cautery or contact Nd:YAG laser. The anterior and posterior folds of the peritoneum are sewn over the cervical stump or stapled with an Endohernia Stapler.™ Once this is completed, the entire abdominal cavity is inspected for any bleeding sites and treated appropriately.

The uterus is removed by bifurcating the uterus with sharp dissection. Removal is accomplished through the umbilical incision, usually necessitating enlarging this incision slightly. However, a fairly large uterus can be removed without extending the incision more than two or three centimeters. After removal of the uterus the fascia is closed down tightly against the trocar sleeve and final inspection of the intra-abdominal cavity is carried out. A posterior culdeplasty may be accomplished at this time by suturing the uterosacral ligaments. The instruments are then removed and trocar sites are inspected for bleeding. The twelve-millimeter ports are closed with a fascial stitch followed by a subcuticular stitch in the five-millimeter ports and the twelve-millimeter ports for skin closure.

A vaginal approach is used to complete the first two types of procedures. To complete the Dodorlein technique, a weighted speculum is placed in the posterior vagina and the anterior cul-de-sac is entered by sharp dissection across the anterior cervix from three to nine o' clock, followed by very minimal blunt dissection. The anterior cul-de-sac is easily entered since the bladder flap has been previously dissected down to the cervix from above. It should be noted that the posterior cul-de-sac is not entered in this technique.

The most significant finding is the ... decrease in postoperative discomfort as expressed by these patients when compared to abdominal hysterectomy, and less than or equal to those with vaginal hysterectomy...

The uterine fundus is grasped with thyroid clamps and pulled through the anterior cul-de-sac along with the adnexa if they have been removed. This exposes the fundus of the uterus through the vagina. The uterine vasculature is then clamped, cut, and tied on either side. The uterosacral ligaments and posterior vagina are then

ligated on either side. With these two pedicles, the uterus is removed. If there is any space left between the two clamps, figure-of-eight suture is then placed through the posterior cul-de-sac and the posterior vagina between the distal ends of the clamps. The vaginal cuff is closed with a running lock suture completing the vaginal portion of the operation. Again, note that the posterior cul-de-sac is never entered separately but is dissected along with the uterosacral ligaments.

In the second procedure the anterior and posterior cul-de-sac is entered via the laparoscope, the cervix is grasped with thyroid clamps for traction, and Haney clamps are used to develop the uterosacral ligaments on either side; then a second and third pedicle are developed up to the area of the previous dissection. If this method is chosen, care must be taken to make certain the dissection from above is in line with the dissection from below so the minimal amount of distance will be traversed.

Thus removal of the uterus, tubes, and ovaries is completed, and the vaginal cuff is closed in the traditional manner. After the vaginal portion of these two techniques is completed, insufflation and revisualization abdominally through the laparoscope is carried out to further observe for any possible bleeding. All bleeding sites are treated with bipolar cautery where necessary and the pelvis is filled with approximately 1500 cc's of Ringer's lactate, which is left in the pelvis to help prevent adhesion formation and also improve bowel function postoperatively. The abdominal incisions are closed as previously described for the supracervical technique.

Results

In these twenty-six patients, there were no intra-operative complications. Fifteen patients were discharged on the first postoperative day, and seven patients were discharged on the second post-op day. Two patients who also had an associated anterior and posterior colporrhaphy stayed three and four days, and one patient who also had a partial thyroidectomy stayed three days. This yields a mean hospital stay of 1.6 days. The mean operative time from anesthetic records was 144 minutes. This included the additional procedures performed in three cases after the hysterectomy was completed.

All patients were called at home on the first day after discharge and were seen in the office two weeks postoperatively if no further complaints were expressed by the patient during the initial follow-up call.

Discussion

In this series of twenty-six laparoscopic hysterectomies, eight were performed using the initially described technique of entering the anterior and posterior cul-de-sac and then going below for a Haney-type vaginal hysterectomy in an average time of 192 minutes. Three hysterectomies were completed using the supracervical technique in an average time of 159 minutes. The remaining fifteen hysterectomies were completed using the Dodorlein technique in an average time of 123 minutes. There is an insufficient number of patients in these categories to make any valid comparison between techniques. Experience gained during the initial procedures also contributed to the shorter operation time for the later procedures which were done with the Dodorlein technique. The average operating time for the first ten patients was 51 minutes longer than for the last ten patients.

The complication rate in these patients was extremely low, with only three patients having a urinary tract infection and one patient having temporary urinary retention. One patient received two units of packed red blood cells. This is a significant improvement over the reported 42.8% complication rate for abdominal hysterectomies and 24.5% for vaginal hysterectomies.[4] Most of these reported complications were febrile morbidity, which did not occur in our group of laparoscopic assisted hysterectomies.

The most significant finding is the significant decrease in postoperative discomfort as expressed by these patients when compared to abdominal hysterectomy, and less than or equal to those with vaginal hysterectomy, although this is a subjective finding and difficult to evaluate. It is felt that some of this decrease in pain may be due to less gathering of tissue in pedicles previously used for abdominal or vaginal surgery and certainly less trauma and physical manipulation with regard to either the abdominal or vaginal hysterectomy. Copious irrigation throughout this process, with minimal amount of bleeding and no blood left in the pelvis at the close of the procedure, may also contribute to the patients' generally better postoperative pain level. Less manipulation of the bowel and certainly minimal to no drying of the abdominal cavity improves postoperative bowel function. This relieves what is often a large problem with postoperative complaints of cramping and "gas pains." Early ambulation may also lead to a decrease in postoperative complications such as thromboembolism and pulmonary embolus. All hysterectomies were performed in the same hospital setting by a single surgeon. As this technique has developed, patients' hospital bills have also decreased as the use of disposable instrumentation has been controlled and operative time has been decreased.

Conclusion

This procedure should be considered for all patients in whom an abdominal hysterectomy is planned. The patient benefits are clear and should be given careful consideration. If a hysterectomy can be completed using a standard vaginal approach and there is no concern for additional pelvic pathology, the laparoscopy may add only minimal additional benefit.

Which of the three techniques is chosen depends on the surgeon's experience. I have found the Dodorlein approach to be quicker to complete, and it is my choice at this time. However, I think the supracervical approach has merit and as the technique evolves, it may become the preferred choice.

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Pancreatic Adenocarcinoma: A Review for Primary Care Physicians

Russell G. Postier, MD, and G. Rainey Williams, MD

Adenocarcinoma of the pancreas is becoming an increasingly common disease. The differential diagnosis of pancreatic adenocarcinoma is that of obstructive jaundice. Suspicious findings on history and physical examination can be confirmed with appropriate laboratory and radiologic testing. Approximately 20% of patients with small lesions and no metastatic disease may be cured with resection. The operative mortality and morbidity for major pancreatic resections is now sufficiently low to warrant a more aggressive approach to these patients.

ADENOCARCINOMA OF THE PANCREAS WAS FIRST described in 1769 by Morgagni.[1] The first operationper formed for this disease was done by Von Winivarter in 1882.[2] For reasons that may be related to the primary risk factors associated with pancreatic cancer, the incidence of this disease has risen dramatically over the past twenty years and it now is the second ranking cause of death among gastrointestinal cancers. These risk factors are advancing age and smoking.[4-8] Molecular biologists have identified at least one oncogene associated with pancreatic adenocarcinoma, the Ki-ras gene, and work is proceeding to better understand the genetic alterations which lead to this disorder.[9] Primary care physicians will continue to see increasing numbers of patients with pancreatic adenocarcinoma. The purpose of this paper is to review the current management of these patients in light of recent advances in diagnosis and therapy.

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Presentation

The majority of patients with adenocarcinoma of the pancreas develop the tumor in the head of the pancreas and present with obstructive jaundice. There is initially little to no pain and the patient may delay seeking medical attention until pain, weight loss, or gastric outlet obstruction become prominent. Patients with tumors in the body or tail of the gland usually present late with pain as their primary symptom. When pain occurs it is usually severe and radiates from the epigastrium to the back. Physical examination usually reveals evidence of icterus and commonly a vague mass in the right upper quadrant of the abdomen representing a distended gallbladder. Signs of recent weight loss, malnutrition, or evidence of ascites all indicate advanced disease. Occasionally, a palpable left supraclavicular node (Virchow's node), periumbilical nodule (Sister Mary Joseph node), or Blummer's shelf may be detected, all indicating advanced disease.[10-12]

The differential diagnosis of pancreatic adenocarcinoma is that of jaundice. Gallstone disease with common duct obstruction, ductal obstruction due to either proximal or distal bile duct adenocarcinoma, or periampullary adenocarcinoma are the most likely alternative diseases. Sclerosing cholangitis, usually in the setting of inflammatory bowel disease, is unusual but is seen. Primary liver disease with jaundice is also a consideration.[12]

Work-Up

Work-up of the patient with jaundice includes appropriate laboratory and radiology testing. It is impor-

tant to select tests in a logical sequence and avoid costly duplication of diagnostic studies. Laboratory examination should include a complete blood count and liver function tests with additional serum total protein and albumin studies to assess nutritional state. Patients with an obstructive pattern, that is, elevated total bilirubin with elevated alkaline phosphatase and only mildly elevated transaminase, need to be further evaluated to determine the site and probable cause of their obstruction.[13] While ultrasound may be used to confirm obstruction by the finding of dilated intrahepatic ducts, it does not preclude the need for further studies. Its usefulness lies in its ability to detect common duct stones as a cause of obstructive jaundice.

Computed tomographic scanning of the abdomen confirms dilated biliary ducts and can usually determine the level of obstruction, i.e., proximal or distal. In addition, the obstructing lesion in the head of the pancreas is usually identified. Presence of metastatic disease in the liver or in peripancreatic nodes, when seen, is helpful in planning treatment.[14] Many authors advocate celiac and superior mesenteric arteriography with portal venous images to aid in the staging of the tumor and identify potentially important anomalies.[15,16] We have not found it necessary to routinely add this expensive, uncomfortable, and potentially risky procedure to the work-up of these patients. Anomalous arterial structures can be detected and protected intraoperatively by experienced surgeons. The accuracy in detecting portal venous or superior mesenteric involvement with tumor has not been sufficient to safely deny potentially beneficial surgery to patients who may be resectable.

If the cause or the location of the obstruction remains in doubt after computed tomographic scanning, then endoscopic retrograde cholangiopancreatography (ERCP) is the next diagnostic step.

Periampullary tumors may be seen and can be biopsied to provide helpful information. Obstruction of both the common bile duct and the pancreatic duct, the double duct sign, if seen, is further evidence for pancreatic cancer as the cause of the jaundice. If ERCP is unsuccessful or fails to adequately indicate the uppermost level of biliary duct obstruction, then percutaneous transhepatic cholangiography (PTC) is indicated.[17]

In the past, PTC and drainage of the obstructive bile ducts prior to definitive operation was routine, but recent data indicate that this increased morbidity and mortality and is not indicated.[18] In most patients, computed tomographic scanning provides adequate information to allow for appropriate treatment, and further studies are not needed. Patients with tumors of the body and tail who present with pain are best evaluated with computed tomography. Unfortunately, the pain usually indicates advanced disease and is not specific enough to lead to an early computed tomographic scan in many cases.

The clinical, laboratory, and radiologic picture of pancreatic adenocarcinoma, especially involving the head of the pancreas, is characteristic enough that therapy can reasonably be instituted in the absence of a tissue diagnosis. In patients with advanced disease or complicating diseases making operation contraindicated, fine needle aspiration cytology using ultrasound or CT guidance usually is able to confirm the diagnosis.[19] This should be avoided in patients who are candidates for operation as it is expensive, uncomfortable, and adds no information that can not be gained at operation. In some cases, a false negative aspiration could delay resection in an otherwise resectable patient.

Therapy

It is now clear that patients presenting with small tumors in the pancreas can be cured with appropriate operations. Tumors less than 2 cm in size and with negative nodes have a 3-year survival rate of over 20% in several series.[20,21] In addition, it is difficult to distinguish preoperatively and even at operation between distal common duct or periampullary adenocarcinomas and pancreatic adenocarcinomas. The former have a nearly 30% 3-year survival rate. The operative mortality rate of the Whipple procedure, which once approached 30%, is now less than 5% in centers with experienced pancreatic surgeons.[20,21] For these reasons, the once nihilistic attitude towards patients with pancreatic adenocarcinoma is no longer warranted. Patients who are unresectable based on preoperative studies or who are otherwise poor candidates for surgery can be palliated either by endoscopically placed biliary stents or stents placed at PTC.[22,23] Endoscopically placed stents are preferred as they obviate the need for an external catheter and simplify the patient's care but are not always technically possible. Gastric outlet obstruction is more difficult to palliate nonoperatively, but in a patient with very advanced disease, a percutaneously placed endoscopic gastrostomy tube is helpful.

Patients who are in reasonable medical condition and have no preoperative evidence of unresectability should be offered an attempt at resection of their tumor. In patients who are unresectable, usually due to invasion of the portal vein or superior mesenteric artery, biliary and gastric bypass and chemical celiac ganglion block can be accomplished and allow for ef-

fective palliation. In resectable patients, the pyloric preserving pancreaticoduodenectomy appears to decrease postoperative morbidity without decreasing the chance for cure.

In the past, prolonged attempts to confirm the diagnosis of adenocarcinoma were made to avoid resection in patients with benign disease. However, the patients with the best chance for cure are the ones in which the diagnosis is most difficult to make because of the small size of their tumors. In addition, there is often an area of pancreatitis surrounding the tumor which is significantly larger than the tumor itself. If an experienced surgeon feels that the operative findings indicate adenocarcinoma, then resection should be carried out without extensive attempts to confirm the diagnosis. In the rare case of pancreatitis masquerading as an adenocarcinoma, the Whipple procedure is a good form of therapy, and thus an unnecessary operation has not been performed. We have had a patient in whom a 5 mm distal common bile duct tumor was resected. We could not have confirmed this diagnosis without resection. The Whipple procedure, once an 8- to 12-hour operation with major blood loss, morbidity, and mortality is now a 3- to 4-hour operation with little blood loss, low morbidity, and low mortality in the hands of experienced pancreatic surgeons.

The majority of patients with adenocarcinoma of the pancreas who are resected will die of disease. Resected patients, however, tend to remain pain free and do well until late in the stages of their disease and are thus better palliated than patients who are bypassed but not resected. Recent data suggests that a statistically significant increase in survival is seen in patients given adjuvant chemotherapy and radiation therapy after potentially curative resection.[24] One must weigh whether this increase in survival is substantial enough to warrant this aggressive therapy and its morbidity to patients who are well palliated with resection alone. We currently offer but do not recommend this therapy to our patients.

The majority of patients who present with pancreatic adenocarcinoma will not be resectable and their therapy is strictly palliative. Nonoperative therapy as previously discussed can effectively eliminate jaundice and its attendant pruritus. While a number of chemotherapeutic and radiation therapy protocols are available to these patients, it is unclear whether they are of any value to the average patient.[25,26] The protocols tend to be aggressive with attendant morbidity and offer only limited extension of life to a small percentage of patients treated. Despite this, a number of patients will be interested in pursuing further therapy.

The most distressing and fearsome problem associated with pancreatic cancer is pain. Epigastric pain radiating to the back due to involvement of splanchnic nerves occurs relatively early in the course of the disease and tends to be severe. A number of techniques are now available which can significantly attenuate the pain in these patients. Celiac ganglion block, done either at laparotomy or via the percutaneous approach, will provide effective, although often short-lived pain relief.[27]

In patients with limited disease but severe pain, a morphine spinal pump offers good pain control. The expense and invasive nature of this approach make it unreasonable for most patients with a limited life expectancy. Patient-controlled narcotic analgesic administered at home via infusaport devices can be very successful in most patients. Finally, narcotic transdermal patches (fentanyl patches) are now available and are being evaluated in this setting. It is important to emphasize to the patient early in the course of their disease that pain control can be achieved and that every effort be made to do so. This can significantly improve the attitude of patients who are facing a terminal illness.

Summary

In summary, patients with adenocarcinoma of the pancreas are being seen with increasing frequency. While most patients will succumb to their disease, resection is now a safe and reasonable alternative in appropriate patients and offers the only hope for cure and the best form of palliation. Resection is best accomplished by surgeons with experience in pancreatic surgery. Nonoperative stenting of the bile ducts can provide palliation in inoperable patients. Currently, chemotherapy and radiation therapy are of limited benefit in this disease. Techniques for pain control are now sufficient to be able to allow the patients in their terminal stages to be relatively pain free.

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(PAID ADVERTISEMENT)

Initial Experience with Single Lung Transplantation in Oklahoma

Norman Imes, MD; David K.C. Cooper, MD, PhD; N. Zuhdi, MD

Inquiries regarding lung transplantation have been made on 89 patients since 1989, of whom 43 have undergone full assessment. Indications for assessment have included chronic obstructive pulmonary disease (including α_1-antitrypsin deficiency), pulmonary fibrosis, and primary pulmonary hypertension. Fourteen patients have undergone single lung transplantation since June 1990 for emphysema, except for one who had pulmonary fibrosis. Twelve remain alive at August 1, 1993, giving an 86% overall survival. All transplanted lungs functioned satisfactorily immediately postoperatively. Mean forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) have improved from 40% and 20% of predicted, respectively, pretransplant to 73% and 61%, respectively, after transplantation. We recommend that lung transplantation be considered in all suitable patients with advanced pulmonary disease.

SINGLE LUNG TRANSPLANTATION HAS BEEN CARRIED out at Baptist Medical Center (BMC) in Oklahoma City since June 1990. Inquiries have been made concerning 89 patients with regard to this procedure, of whom 43 have undergone full assessment for transplant suitability. Twenty-three were accepted for lung transplantation, four of whom have died awaiting a suitable donor. Twenty patients were declined because contraindications were present that would have jeopardized the success of the procedure. Several other patients, whose pulmonary disease was not yet considered advanced enough to warrant transplantation, continue to be followed with lung transplantation as the ultimate goal.

To date, fourteen patients have undergone single lung transplantation. Twelve of these patients are alive as of August 1, 1993. We briefly describe this initial experience with single lung transplantation in Oklahoma.

Indications for Single Lung Transplant

Patients considered for single lung transplantation must have end-stage pulmonary or pulmonary vascular disease. The major indications are outlined in Table 1. (Lung disease characterized by bilateral infection must be treated by bilateral lung transplantation in order to remove all septic tissue.) In our own experience, the most common reason for referral has been chronic obstructive pulmonary disease due to emphysema. Several of these patients have α_1-antitrypsin deficiency.

The contraindications for lung transplantation are outlined in Table 2 and, in general, are similar to those for heart transplantation.

We have restricted single lung transplantation to patients under the age of 65 years, although we would not rule out older patients on age alone. However, with advancing age, assessment of patients is necessarily strict. Patients with primary pulmonary hypertension are at higher risk from immediate post-transplant mortality and morbidity, and, therefore, we believe that assessment should similarly be particularly rigorous and include only younger patients. Although we have not yet carried out transplantation in such a patient,

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we have assessed several and should soon perform our first transplant for this condition.

Patient Population

Eight of the 14 patients were female and 6 were male (Table 3). Their ages ranged from 48 to 63 years (mean 54 years). All but one had chronic obstructive pulmonary disease, with two of these being α_1-antitrypsin deficient. The remaining patient had idiopathic pulmonary fibrosis. All required continuous or intermittent oxygen therapy and corticosteroid therapy. The average waiting period for a suitable donor was 8 months (range 1-17 months). Postoperative follow-up has ranged from 1 week to 37 months.

Results

There has been only one technical complication due to oozing from the left atrial anastomosis which required reopening of the chest. All donor lungs have functioned well immediately post transplantation with patients requiring postoperative positive pressure ventilation from 9 hours to 9.5 days (mean 2.25 days). Post-transplant hospital stay has ranged from 9 to 24 days in all but one patient (Table 3). The longest stay (50 days) was in a man who was greatly debilitated pretransplant with significant cachexia and muscular atrophy. He required prolonged rehabilitation but is now doing very well. There have been two early deaths and no late deaths (Table 3). Overall survival is presently 86% (12 of 14).

Our third transplant patient developed a moderately severe acute rejection episode during the first 3 weeks, which required therapy with high doses of methylprednisolone. Although the acute rejection was completely resolved, she subsequently developed a Gram-negative septicemia (from urosepsis) from which she died at the end of the second post-transplant month as a result of multiple system failure. Because of this experience, we modified our maintenance immunosuppressive program, and no further episodes of acute rejection have occurred during the first 3 months.

The second death (Patient 5) was from a massive pulmonary embolus that occurred in a patient who had made an excellent posttransplant recovery and was ready to be discharged home on the 14th day. The embolus resulted in severe hemodynamic and respiratory compromise and he died from multi-organ failure on the 24th post-transplant day. All subsequent patients have received low-dose intravenous heparin beginning in the immediate post-transplant period and continued until discharge from hospital. No further emboli have occurred.

Patient 7 developed ischemic necrosis in the anterior wall of the bronchus intermedius of the donor lung. This has resulted in granulation tissue and stricture below the anastomosis of the donor and recipient airways. Repeated bronchoscopic laser removal of granulation tissue and balloon dilatation (performed by his referring pulmonologist, Dr. Dennis Parker) have been required. However, he remains fully functional and there are indications that the formation of granulation tissue is declining.

The only other late complication of significance was an acute rejection episode (Patient 2) that developed

Table 1. Indications for Single Lung Transplantation

End-stage pulmonary disease with a life expectancy of <24 months.

***Common* indications include:**

a. Chronic obstructive pulmonary disease (including α_1-antitrypsin deficiency)
b. Idiopathic pulmonary fibrosis
c. Primary pulmonary hypertension

***Other* possible indications include:**

d. Hypersensitivity pneumonitis
e. Occupational fibrotic lung disease
f. Drug/toxin-induced fibrotic lung disease
g. Sarcoidosis
h. Bronchiolitis obliterans
i. ?Scleroderma

Cystic fibrosis, bronchiectasis, eosinophilic granuloma, and lymphangioleiomyomatosis are indications for double lung transplantation

Table 2. Contraindications for Single Lung Transplant

1. Impaired left ventricular function or significant coronary artery disease (investigated by cardiac catheterization in patients >40 years).
2. Significant peripheral vascular or cerebrovascular disease.
3. *Irreversible* severe dysfunction of any other major organ (e.g. kidneys, liver).
4. Coexisting systemic illness that may limit life expectancy or jeopardize post-transplant recovery.
5. Poor rehabilitation potential (despite patient's participation in a preoperative rehabilitation program).
6. Current drug addiction, alcoholism, mental illness, or psychological instability.
7. *Untreated* or *recent* malignancy.
8. *Active* peptic ulcer disease.
9. *Uncontrolled* diabetes mellitus.
10. *Active* infection (except within the lung to be removed).
11. Previous lobectomy or surgical pleurectomy on the side of transplantation.
12. Age >65 years.
13. Continued smoking.

23 months after transplantation following an episode of cytomegalovirus (CMV) pneumonitis. Three other patients have required therapy with ganciclovir for mild CMV pneumonitis, and have done well without precipitation of rejection episodes.

Transplant patients must participate in pulmonary rehabilitation both before and after transplantation. All patients have experienced a significant improvement in pulmonary function tests after transplantation. Mean pre-transplant forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) in the 14 patients transplanted was 1.57L (40% of predicted) and 0.57L (20% of predicted), respectively (Table 4). Mean post-transplant figures for FVC and FEV_1 have risen to 2.74L (73%) and 1.77L (61% of predicted), respectively (Table 4).

Table 3. Single Lung Transplants at Baptist Medical Center (June 1990 - July 1993)

Pt	Age	Sex	Diagnosis	Date of Tx	Hospital Stay	Outcome
1	54	F	COPD	6/23/90	14 days	Alive
2	55	F	COPD	2/18/91	15 days	Alive
3	52	F	Pulmonary fibrosis	3/12/91	21 days	Died (53 days) Gram negative septicemia
4	58	M	COPD	8/20/91	22 days	Alive
5	50	M	COPD	9/22/91	24 days	Died (24 days) Pulmonary embolus
6	49	F	COPD	10/13/91	12 days	Alive
7	52	M	COPD	4/1/92	9 days	Alive
8	48	F	COPD	9/21/92	17 days	Alive
9	49	F	COPD	1/15/93	14 days	Alive
10	59	M	COPD	2/13/93	50 days	Alive
11	53	M	COPD	2/25/93	16 days	Alive
12	63	F	COPD	7/11/93	*	Alive
13	48	F	COPD	7/16/93	*	Alive
14	60	M	COPD	7/24/93	*	Alive

COPD = chronic obstructive pulmonary disease

* Remains as an inpatient on 8/1/93

Discussion

We have been encouraged by the good results obtained in this initial series, particularly in the last 9 consecutive patients. The early changes we made to our immunosuppressive regimen and the introduction of anticoagulation while the patient

Table 4. Pre- and Post-Transplant Forced Vital Capacity (FVC) and Forced Expiratory Volume in One Second (FEV1) in Patients Undergoing Single Lung Transplantation

	Pretransplant				Post-Transplant			
Patient	FVC	(% Predicted)	FEV_1	(% Predicted)	FVC	(% Predicted)	FEV_1	(%Predicted)
1	1.25L	(39%)	0.43L	(16%)	2.76L	(84%)	2.09L	(89%)
2	1.15L	(39%)	0.38L	(17%)	1.92L	(71%)	1.23L	(55%)
3(a)	1.13L	(35%)	1.06L	(43%)	2.21L	(73%)	1.71L	(66%)
4	0.93L	(18%)	0.42L	(11%)	4.47L	(90%)	2.75L	(74%)
5	2.11L	(40%)	0.61L	(15%)	(b)			
6	1.36L	(44%)	0.43L	(16%)	2.45L	(77%)	1.45L	(55%)
7	1.34L	(26%)	0.44L	(11%)	3.06L	(60%)	1.52L	(41%)
8	0.96L	(33%)	0.45L	(18%)	2.28L	(77%)	1.46L	(59%)
9	1.36L	(37%)	0.64L	(23%)	1.88L	(61%)	1.44L	(54%)
10	3.03L	(63%)	0.76L	(22%)	3.44L	(78%)	2.30L	(69%)
11	3.02L	(63%)	0.96L	(26%)	2.88L	(60%)	1.71L	(47%)
12	1.53L	(54%)	0.66L	(28%)	(c)			
13	0.81L	(24%)	0.25L	(10%)	(c)			
14	2.06L	(50%)	0.57L	(18%)	(c)			
	Mean (n=14)				Mean (n=10)			
	1.57L	(40%)	0.57L	(20%)	2.74L	(73%)	1.77L	(61%)

(a) Idiopathic pulmonary fibrosis. All other patients had emphysema.

(b) Died too early post-transplant to assess.

(c) Alive, but too early post-transplant to assess.

is hospitalized would appear to have been beneficial factors in these improved results.

These early results compare satisfactorily with the available worldwide figures,[1,2] which show a 60-day mortality of approximately 20%, with a one-year survival of just under 70%. Patients with idiopathic pulmonary fibrosis or primary pulmonary hypertension tend to do less well than those with emphysema. Similarly, patients requiring bilateral lung transplantation also have a higher early mortality. For these reasons, we have concentrated our initial efforts on those with chronic obstructive pulmonary disease although we are now listing patients with other conditions that will require bilateral lung transplantation.

The long waiting periods for a suitable donor organ (which is a problem common to all lung transplant programs in the U.S.A. today) have led us to encourage physicians to refer patients for this procedure at an earlier, rather than later, stage in the disease process. Fortunately, emphysema and pulmonary fibrosis are conditions that usually progress slowly, but four patients have died awaiting a suitable donor organ.

The severe limitation of the number of donors available for lung transplantation is largely related to the high incidence of pulmonary infection in brain-dead patients being maintained on ventilators. To date, only one donor lung has been retrieved from centers in Oklahoma, the remainder being obtained from other states.

The number of patients undergoing single or bilateral lung transplantation in the U.S.A. has rapidly increased during the past few years from 33 in 1988 to 535 in 1992. Currently, just over 1000 patients await these procedures in the U.S.A.

Our initial experience has encouraged us to believe that lung transplantation has a major role to play in the management of patients with end-stage lung disease, and can offer such patients a greatly improved quality of life for several years. We recommend that it be considered in all suitable patients with advanced pulmonary disease where there are no obvious contraindications.

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Health Care Tips for Your Professional Corporation

or

Where There Is a Buy-Sell Agreement, There Is a Way

Robert W. Gaddis

I'M A BUSINESS LAWYER WITH AN EMPHASIS ON HEALTH law. When I started practicing over twenty years ago, some of my first clients were physicians and professional corporations. Indeed, one of my early legal publications (almost twenty years ago) was a two-part article on a tax-favored transaction for physicians which appeared in the JOURNAL. (A real estate transaction for the physician and his children, 66 *J Okla State Med Assn* 488, 1974; A real estate transaction for the physician and his children—II, 67 *J Okla State Med Assn* 380, 1974.)

When you've practiced law for over twenty years dealing with sophisticated, well-educated individuals and complex transactions, you witness facts and circumstances far more fanciful than even the most creative fictional machinations.

This is true even (probably *more so)* in the professional corporation environment.

Physicians are intelligent, well-educated, forthright individuals with a high degree of self confidence. Thank goodness. When focused on the healing arts, these personality attributes can achieve the miracles of modern medicine the public has come to expect. When focused on a divisive professional setting, these personality traits can, likewise, precipitate the hostile, protracted negotiation and litigation scenarios with which we all are familiar.

The most efficacious regimen for avoiding these nasty encounters, in my opinion, in the professional corporation (PC) environment, is the tandem utilization of well-reasoned and artfully drafted Buy-Sell Agreements with properly structured Employment Contracts. (Many of the concepts also apply to the partnership setting. However, for didactic purposes, my discussions herein will refer only to PCs.)

I have concluded, from my experience over the years, that probably the most important document I prepare in my practice is the Buy-Sell Agreement. This is true for all business settings, but it is particularly applicable to PCs due to the strong personalities typically involved.

Additionally, with federally mandated changes for the delivery of health care services on the horizon, these documents have even greater importance. Since most of the suggested "reforms" tend toward some form of "competitive managed care," more and more physicians will be involved in group practices. Such practices, whether large or small, may become, under the various proposals, units of larger managed care groups. In any event, the significance of the documentation for entity formation and its relationship with its physician employees will doubtless assume greater significance under almost any of the conceivable health care "reforms." Thus, the focus on these documents and the planning for their implementation is timely.

Upon formation of a PC or the admission of a new physician/shareholder, there is typically optimal harmony between the parties. At this juncture the parties can usually agree upon the terms for a Buy-Sell Agreement.

Later, when fact circumstances have arisen which may bring the Buy-Sell Agreement into operation, or divisive events have occurred within the PC, there is,

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not unexpectedly, less than full harmony among the shareholders. Indeed, in my experience, even in the most benign of circumstances (e.g., a garden variety shareholder retirement), there is at least some tension because the remaining shareholders are now having to *fund an obligation with hard dollars* rather than rhetorically articulating the concept as was the case in the formative stages.

At the other end of the spectrum, I have witnessed extremely rancorous PC shareholder withdrawals where all parties had attorneys and eventually ended up in court. In this scenario, it is not unlikely for the combined legal fees for the various parties to ultimately exceed the total amount originally in dispute.

In my opinion, the key to avoiding these situations is providing proper structural documents, carefully defining the relationship between the PC and its shareholders.

The importance of this strategy cannot be overly emphasized. With a well-reasoned plan and a documented blueprint for the PC's structure for ingress and egress of its shareholders, the stress, anxiety, *and expense* of shareholder withdrawal can be minimized.

In today's regulated and litigious medical practice environment, the physician is frequently taxed to the maximum just with the practice of medicine. When added to these demands, the pressures from a confrontational PC or partnership breakup may preoccupy and cloud the physician's decision-making capability, sometimes affecting the physician's medical practice.

My comments are an attempt to help the physician avoid such difficult situations. This article is divided into two parts, with Part II published in a later issue of the JOURNAL. Part I deals with the PC's Buy-Sell Agreement and my suggestions for this document, while Part II will discuss the PC's shareholder Employment Contract.

The Buy-Sell Agreement

A. General. "Buy-Sell Agreement" is a generic term I use to describe the document governing the repurchase of shares from a withdrawing or deceased shareholder. These agreements can take various forms. However, the underlying common denominator for such instruments is that they provide a written plan (and *a purchase price)* for handling the repurchase of shares of a withdrawing or deceased shareholder upon the occurrence of specified "Events."

In the PC environment, Buy-Sell Agreements will typically take the form of a "redemption" where under the PC (to the extent it is not insolvent or is otherwise under no legal disability) is obligated to repurchase the withdrawing shareholder's shares. I refer to these documents as "Stock Redemption Agreements."

Although there are other structures pertaining to the purchase of a withdrawing shareholder's shares (for example, a Cross Purchase Agreement between shareholders where the remaining shareholders are obligated to purchase such shares), I have never used an agreement other than a Stock Redemption Agreement for PCs during my career.

This result is not surprising since the facts and circumstances pertaining to the PC generally suggest utilization of a Stock Redemption Agreement, rather than other legal modalities.

The following discussion analyzes the more important provisions of the PC Stock Redemption Agreements I use in my practice. To facilitate this analysis, I have included, in some instances, specimen contract language for the reader's consideration. Additionally, I have attached, as Attachment A, a specimen Table of Contents to provide the reader with an overview of the Stock Redemption Agreement.

B. Recitals. "Recitals" are introductory language at the beginning of a contract to explain the general facts and circumstances applicable to the agreement. You have perhaps seen this language in the form of "Whereases" with each "Whereas" setting forth part of the background for the transaction. For example, you might have seen language such as the following:

> WHEREAS, the corporation is a professional corporation organized under the laws of the State of Oklahoma, and is authorized to engage in the business of providing medical and surgical consultation, diagnosis, care and treatment, and services ancillary thereto through duly licensed physicians and surgeons employed by the corporation; and
>
> WHEREAS, the corporation's primary area of practice is in [name of specialty] and medical services related thereto...

Modern drafting techniques omit utilization of "whereas" for such information. Today, these facts are usually in paragraph form at the beginning of the agreement prior to the actual covenants. Although recitals may not technically be true "covenants" pertaining to the agreement, courts may view recitals as interpretative guidelines for the document and the circumstances pertaining to its creation.

In this connection, one of the important emerging issues today is physician "credentialing." Although credentialing is usually regarded as a process for hospital medical staff admission, it is becoming an issue for PCs and managed care entities. Therefore, I also include a recital similar to the following in Stock Redemption Agreements:

> Each shareholder is duly licensed under the laws of the State of Oklahoma to practice medicine as a physician and surgeon, is in good standing with the Oklahoma State Board of Medical Examiners, and is board-certified in _____ by the _____.

This provision, in addition to stating the minimum qualification requirements for the practice of medicine, also contains a recital pertaining to "good standing." The "good standing" language would prevent the physician from making such a representation if the physician were under any kind of licensure revocation or suspension. Moreover, I require that a recent letter of good standing be attached as an exhibit to the physician's Employment Contract at the time of execution.

Medical staff credentialing for managed care organizations and PCs is an emerging issue which, no doubt, will generate further theories of legal liability for such entities. Although the PC and its shareholders may be well insured for medical malpractice purposes, such insurance will not, generally, cover non-medically related injurious acts of its physician shareholders. Therefore, credentialing becomes especially important since claims arising for non-medical malpractice circumstances may create corporate liabilities which will have to be paid from shareholders' earnings.

C. Restrictions Against Transfer. These provisions typically provide that the PC's shares may not be transferred except in accordance with the terms of the agreement.

D. Events Requiring Sale of Shares. This language defines in detail the "Events" upon which a shareholder will be required to sell shares pursuant to the terms of the agreement. The following is illustrative of the language I use for this provision:

> Each Shareholder does hereby covenant and agree for himself, his heirs, and legal and personal representatives, that upon the happening of any of the following events, the Shareholder or his legal or personal representative shall sell and transfer all of his shares to the Corporation or to the remaining Shareholder(s) if (a) the Corporation cannot lawfully purchase the Shares, or (b) such purchase would give the Corporation a negative net worth; and the Corporation or the remaining Shareholder(s) shall purchase all, but not less than all of the Shares of stock in the Corporation then held by such Shareholder at a price determined in the manner provided in Section ___ below and upon the terms herein set forth:
>
> A. The death of the Shareholder; or,
>
> B. Whenever the Shareholder shall cease to be a licensed physician and surgeon under the laws of the State of Oklahoma or any other state in which the Corporation is authorized to engage in business or the practice of medicine and surgery, or whenever the Shareholder is otherwise disqualified to or suspended from the practice of medicine and surgery under the laws of Oklahoma or any other state in which the Corporation is authorized to engage in business or the practice of medicine and surgery; or,
>
> C. If the Shareholder, because of mental, physical, or other disability, is unable to fulfill his duties and responsibilities as prescribed by his Employment Contract on a full-time basis for a period of ninety (90) [or such other period as the PC elects] days after the date of his initial disability ; or,
>
> D. The voluntary withdrawal or retirement of the Shareholder from the practice of medicine and surgery; or,
>
> E. The withdrawal for any reason by the Shareholder from the active practice of medicine and surgery with the Corporation and commencement of such practice alone or in the company of others not in the employ of the Corporation; or,
>
> F. The failure of the Shareholder to return to full-time employment of the Corporation in his professional capacity as a licensed _____ [specialty] within ninety (90) days after termination of military service; or,
>
> G. In any event upon the termination of employment of the Shareholder with Corporation for any reason or cause.

These provisions are more or less self-explanatory and define the "Events" upon which shares must be repurchased. Clause G, "repurchase upon termination of employment," is a particularly important provision, since the Employment Contract will contain detailed provisions pertaining to employment termination. Thus, in the event of a shareholder's misconduct, and termination of his employment with the PC pursuant to the terms of the shareholder's Employment Contract, the PC would then be obligated to repurchase such shareholder's shares. This is the desired result, since the remaining shareholders would not wish to have amongst their group a shareholder who was no longer employed by the PC.

E. Purchase and Sale. These provisions are likewise important and define the PC's obligation to repurchase the shares. If the PC is under a legal disability and cannot repurchase such shares from "earned surplus," then the shareholders, pro rata, become obligated to purchase such shares.

I typically use the following, or a variation thereof, for this provision:

> Upon the occurrence of any of the events specified in Section _____ above, the Corporation agrees to purchase and each Shareholder agrees to sell and transfer to the Corporation all of his Shares. The Corporation shall purchase all of that Shareholder's Shares on the terms and conditions and for the consideration set forth herein. The Shareholders, and each of them, agree for themselves and their legal representatives, heirs, and assigns, to sell their Shares upon the happening of any of the aforementioned events under the terms and conditions and for the consideration set forth herein. The obligation of the Corporation herein to purchase the Shares of any Shareholder is specifically conditioned upon such purchase by the Corporation being lawful under the Statutes of the State of Oklahoma, the Articles of Incorporation of the Corporation and its Bylaws in effect at the time of the occurrence of the event requiring such purchase. If, at the time of the occurrence of the event requiring such purchase and sale, such purchase would give the Corporation a negative net worth and/or the Corporation is prohibited by its Articles of Incorporation or Bylaws or by law to purchase

all of the Shares of stock of the involved Shareholder or Shareholders, then the remaining Shareholder or Shareholders, pro rata, shall have the right and be obligated to purchase such Shares, and if there be more than one remaining unaffected Shareholder, each remaining Shareholder shall purchase such Shares of the selling Shareholder or Shareholders in the proportion that the total number of Shares to be purchased and sold bears to the total number of Shares of capital stock of the Corporation owned by all such remaining Shareholders. The price at which such remaining Shareholders shall purchase such Shares and the terms of purchase shall be the same as those imposed herein upon the Corporation had the purchase by it not been in violation of law or its Articles of Incorporation or Bylaws.

F. Purchase Price Determination. Obviously, this is the bedrock of the Stock Redemption Agreement. Purchase price determinations can be debated at length with various evaluation scenarios. The typical issue that first arises in such discussions is whether or not there is "good will" value attributable to the PC's shares in excess of the actual book value.

I have participated in many conversations on this topic and believe, in my opinion, there should be very little or no good will ascribed to shares in the typical PC environment with ten or fewer shareholders.

Indeed, for the purposes of division of marital property, in the case of *Mocnik v. Mocnik,* 838 P. 2d 500 (Okla. 1992), the Oklahoma Supreme Court appears to have held there is no "good will," absent an agreement to the contrary, in a medical practice for purpose of division of the marital estate. *See also* "Division of Good Will of Medical Practice as a Marital Asset," Richard B. Noulles and Pamela S. Anderson, Vol. 63, *OBAJ* No. 49, p. 3851 (December 31, 1992).

I normally suggest a "net book value" determination approach, with receivables excluded from net book value, since shareholders' receivables can be dealt with in the Employment Contract in the form of "termination compensation." The following is illustrative of the provision I use in this regard:

MANNER OF DETERMINATION OF PURCHASE PRICE.

Determination of Purchase Price of Shares of Stock.

A. Upon the occurrence of an event requiring a purchase and sale of the Corporation's stock pursuant to this Agreement, the price to be paid for such stock shall be the issued and outstanding per share adjusted book value as hereinafter defined, multiplied by the number of shares to be purchased and sold. Said price shall be determined and computed as of the last day of the calendar month preceding the month in which the event requiring a purchase and sale occurs or in which an option to purchase is exercised. Determination and computation of the purchase price to be paid shall be made by the Corporation's regular Certified Public Accountant from the books and records of the Corporation utilizing generally accepted accounting principles consistently applied. Such determination and computation shall be final and binding upon the parties hereto, their respective heirs, legal and personal representatives, successors and assigns, except for mathematical errors. In determination of the adjusted book value, the accountant making the same shall, however, observe the following:

(i) No allowance of any kind shall be made for goodwill or any similar intangible asset of the Corporation;

(ii) There shall be excluded any insurance proceeds payable to the Corporation by reason of the death of any Shareholder;

(iii) There shall be excluded all accounts receivable of the Corporation; and

(iv) Accumulated depreciation on all the Corporation's furniture, fixtures, equipment, and leasehold improvements shall be calculated using [insert Corporation's formula for this determination].

B. In the event any additional accounting charges are incurred in determination or computation of the purchase price to be paid the selling Shareholder or his legal or personal representative, such charges shall be paid by the Corporation.

In addition to the obvious mechanical and pragmatic concepts presented in this language, Paragraph (B) is important since it fixes liability for additional accounting charges in the event of a dispute.

G. Terms of Payment. These provisions relate to the method of paying the withdrawing shareholder or such shareholder's personal representative for the purchased shares. I typically suggest something in the nature of 25% in cash, with the balance payable pursuant to the terms of a Promissory Note for a period of two to four years with a reasonable rate of interest. The longer payout scenario is routinely used for retirement or "voluntary withdrawal." The shorter term is used for death and disability.

In this regard, I suggest the PC obtain and maintain adequate life insurance to not only fund the Buy-Sell Agreement, but to also provide the PC with additional insurance in the form of "key man" insurance covering its shareholders in the event of death or disability. Although the repurchase price under the Buy-Sell Agreement may not be substantial due to the removal of receivables from the valuation formula, it has been my experience, in the event of the death or disability of a shareholder, that the PC *always* incurs additional unforeseen expenses.

When considering such eventualities, the parties routinely believe overhead will decrease immediately. Such is not the case. Rent and equipment payments will continue. Usually there is little opportunity to make immediate staff cuts to reduce overhead.

Moreover, the remaining shareholders and the PC's administrator will have increased responsibilities in winding up the deceased or disabled shareholder's business affairs and medical practice—not the least of which will include seeing patients and *collecting receivables.* Therefore, I am a strong advocate of fund-

ing the Buy-Sell Agreement with life and/or disability buy-out insurance, as well as providing a minimum amount of key-man insurance on each physician. In a typical PC with four to six physicians, I suggest at least $50,000 of key-man insurance for each physician.

H. Notice. Another provision that should be included in the Buy-Sell Agreement is a requirement that a withdrawing shareholder provide the PC with a minimum amount of notice of such shareholder's intent to withdraw from the PC.

The "notice" provision is to protect the PC and to provide it with adequate time to plan for a wind-down of the withdrawing shareholder's practice and/or to find a replacement physician to assume such shareholder's medical responsibilities. Generally, in the event the withdrawing shareholder fails to provide adequate notice, some penalty provision is included to reduce the price such shareholder would otherwise receive for his/her shares. The following is illustrative of this concept:

> Due to Corporation's obligation to provide high quality care to its patients and the lengthy time and expense required to obtain a suitable replacement [name of specialty], and to encourage adequate notice from the Shareholders to assist Corporation in meeting its obligations, notwithstanding anything herein contained to the contrary, a Shareholder whose withdrawal or retirement from the Corporation is at his sole and voluntary election, must provide the Corporation with three hundred sixty-five (365) days' written notice of his intent to terminate his affiliation with Corporation. Unless such notice is given, said Shareholder shall be responsible for an overhead charge, subsequent to his withdrawal or retirement, determined by the Corporation's regular accountant as follows:
>
> [Insert formula determining charge]
>
> Any such sums due the Corporation may, at the Corporation's election, be deducted from any sums due a selling Shareholder from the Corporation, for any reason whatsoever, and/or pursuant to this Agreement.

I. Election to Dissolve. This is a unique provision I sometimes include in Buy-Sell Agreements, when two or more shareholders withdraw from the PC within a six-month period, to provide the remaining shareholders an option to dissolve the PC, in lieu of repurchasing shares from the withdrawing shareholders. I refer to this provision as a "safety valve" provision since it gives the PC protection from possible financial hardship when two or more shareholders may elect to split off from the PC at the same time—or in the event of other unlikely occurrences such as a common disaster. Although this provision subverts the purpose of the Buy-Sell Agreement, it protects the remaining shareholders from unforeseen circumstances. The following language is illustrative of this provision:

> Notwithstanding anything herein contained to the contrary, in the event two or more Shareholders (or the legal representative(s) thereof) should tender their Shares for redemption hereunder within any consecutive six-month period, a majority of the then remaining Shareholders may elect to dissolve the Corporation, in accordance with the laws of the State of Oklahoma then in force, in lieu of redeeming Shares pursuant to the terms hereof. Such election shall be at the sole discretion of a majority (excluding any Shareholder(s) seeking redemption) of the then remaining Shareholders.

J. Consent and Approval of Spouse. This is an important concept, and we typically suggest execution of a "spousal approval certificate," whereby each shareholder's spouse approves and agrees to the terms of the Buy-Sell Agreement. This approval has proved useful many times, and is helpful, not only in divorce settings, but in repurchasing shares of a deceased or disabled shareholder. The following is demonstrative of the "spousal consent" we usually suggest:

> SPOUSAL CONSENT
>
> I acknowledge that I have read the foregoing Stock Redemption Agreement ("Agreement") and that I know and understand its contents. Also, I am aware under its provisions that my spouse agrees to hold his shares of capital stock ("Shares") of _____ (the "Corporation"), an Oklahoma professional corporation, subject to certain restrictions, and to sell the Shares, including my interest in them, upon certain events. I hereby approve of the provisions of such Agreement and consent to such sale; I agree that I shall not make any transfer of, or otherwise deal with, the Shares or my interest therein during my lifetime, except as expressly permitted by such Agreement. Upon my death, I agree that I shall not make any transfer of, or otherwise deal with, my interest in the Shares, if any, whether by bequest or by the application of the residuary clause of my Will or otherwise, in any manner which would cause the Shares to cease being subject to such Agreement.
>
> _____
> [Spouse's Signature]

J. Miscellaneous Covenants and Agreements. In addition to the garden variety "miscellaneous" provisions, we typically include an attorney's fee provision in our Buy-Sell Agreements as follows:

> Attorneys' Fees. Upon the breach of any covenant contained herein, the aggrieved party shall have the right to pursue such action in law or in equity as such party deems appropriate. The party prevailing in such action shall be entitled to his or its reasonable and necessary costs, expenses, and attorneys' fees associated herewith.

Although this provision is a double-edged sword, in the event of a dispute, we believe this provision keeps the parties at the bargaining table and prevents a precipitous, knee-jerk flight to the courthouse.

Another miscellaneous provision I include relates to accounting matters. In this regard, I generally suggest the following:

> Accounting Matters. All accounting matters and financial calculations to made hereunder shall be made by Corporation's regular accountant utilizing the accounting practices adopted by Corporation from time to time. The parties hereto agree to be bound by such calculations.

This provision, in conjunction with the accounting language under the "Determination of Purchase Price" provision, is intended, absent fraud or other illegal circumstances, to bind the parties to the accounting determinations made by the PC's regular accountant. This is appropriate since the PC's regular accountant is familiar with the PC's financial structure, and, in most cases, has been involved with the PC's books and records for an extended period of time.

Conclusion

The foregoing remarks and specimen language are illustrative of my approach to the PC's Buy-Sell Agreement based upon my experience and background. Fortunately, our firm has never had to litigate a PC shareholder separation. A well-drafted Buy-Sell Agreement is, indeed, a sound prescription for good corporate health.

In my next article I will analyze the physician/shareholder Employment Contract and its interrelatedness to the Buy-Sell Agreement. That article will also include a discussion (and specimen language) for handling a shareholder's receivables in the form of "termination compensation," since, in this article, I suggest excluding receivables from the purchase price determination under the Buy-Sell Agreement.

Acknowledgment

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The Author

Mr. Gaddis is vice-president and a director of the Tulsa law firm of Barrow Gaddis Griffith & Grimm, Inc.

ATTACHMENT A

[NAME OF PROFESSIONAL CORPORATION]
STOCK REDEMPTION AGREEMENT
[Date]

SPECIMEN

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Guardianship in Oklahoma for Purposes of Medical Consent

Teresa Meinders Burkett

This article summarizes the various forms of guardianship available in Oklahoma for purposes of consenting to medical procedures.

Guardianships Available Under Oklahoma Law

Oklahoma law provides for general guardians, limited guardians, and special guardians. Each type of guardianship is supervised by the court in which the guardianship proceeding is filed. The legal definition of a guardian is a person appointed by the court to take care of the person or property of another. The person over whom a guardian is appointed or over whose property a guardian is appointed is called a ward. A general guardianship is the broadest form of guardianship available and requires the guardian to post a bond and file annual reports with the court to keep the court advised as to the status of the ward's person and property under the guardian's control.

A limited guardianship is similar to a general guardianship. However, a limited guardian only has limited powers over the person of the ward and over only certain property of the ward as specified by the court. A special guardianship is a guardianship that lasts for a period of ten to thirty days and may be ordered for a person who is incapacitated or partially incapacitated when there is imminent danger to the health or safety of the person unless immediate action is taken. When a guardianship is proposed for the limited purpose of consenting to a specific medical treatment, I have recommended that family members attempt to become special guardians of the person.

Persons Over Whom a Guardianship May Be Ordered

A guardianship may be initiated to protect an incapacitated person who is at least eighteen (18) years of age. The legal definition of an incapacitated person is a person who is impaired by mental illness, mental retardation or developmental disability, physical illness or disability, drug or alcohol disability, or some other similar cause, and whose ability to receive and evaluate information effectively or to make and to communicate responsible decisions is impaired to such an extent that the person lacks the capacity to meet the essential requirements for his or her physical health and safety. The term "incapacitated person" is equivalent to the term "incompetent person," including a person who has been found legally incompetent by the court. Minors may also be the subject of a petition requesting the appointment of a guardian, limited guardian, or special guardian.

Powers of the Guardian

A general guardian has broad control over the person and property of the ward except as specifically limited by statute or the court. A limited guardian has only those powers over the person or property of the ward that the court specifically grants. A guardian of the person, including a special guardian, is charged with the custody of the ward and must provide for his or

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her medical care. After a petition for guardianship has been filed, the court will execute letters of guardianship, which are legal documents giving the guardian authority to act. The court will set forth in the letters or in a separate order the powers which are extended to the guardian. For medical consent purposes, you should review the guardian's papers to determine whether the guardian is authorized to make health care decisions. A general guardianship confers on the guardian the right to consent to medical treatment without specific language to that effect. However, a guardian may only make decisions regarding the withholding or withdrawal of life-support if specifically given that power in a separate court order.

The Oklahoma Hydration and Nutrition for Incompetent Patients Act states that no guardian may authorize the withholding or withdrawal of artificial nutrition or hydration unless the court finds there is "clear and convincing evidence" that the ward decided that he or she would want such sustenance withheld while competent to make that decision. This standard would be difficult to meet unless the ward signed a living will directing such a decision while competent to do so.

Priority for Selection of the Person to Serve as Guardian

The court has the right to select the person who will serve as a guardian of a proposed ward. The first choice will go to an individual nominated by the proposed ward in writing prior to his or her incapacity. Next, the court will consider a person who is already appointed the limited guardian of the person, then an individual nominated by the will or other writing of a deceased parent, spouse, or adult child who was serving as a guardian of the ward prior to the proceeding. Next in priority is the spouse, adult child, parent, or sibling of the person. Finally, the court may appoint any individual approved by the court with whom the proposed ward has been living for at least six months prior to the filing of the petition. This person cannot be the owner or administrator of a nursing home or other long-term care facility unless the person is otherwise related to the proposed ward.

Notice of Hearing

The court will give notice to the proposed ward and his or her spouse, attorney, adult children, parents, and all adult brothers and sisters as to the time and place of the hearing on the petition for guardianship. Notice will also be given to the proposed guardian, if that person is not the petitioner, and to the person or facility having care or custody of the proposed ward. The notice must be personally served on the proposed ward at least ten (10) days before the time set for hearing. All others entitled to notice must be served by regular first-class mail. The notice must be mailed at least ten (10) days prior to the time for hearing. Upon a showing of good cause, the court may shorten the notice period. The notice which must be sent is specifically set forth in the Oklahoma Statutes. At the hearing on the petition, the court will determine whether or not it is necessary to appoint a guardian of the person of the proposed ward. If a guardian is needed, the court will determine whether a general or limited guardianship is required.

Appointment of a Special Guardian

The court may appoint a special guardian for a person who appears to be or has been found to be an incapacitated or partially incapacitated person, when it appears that there is imminent danger that the health or safety of the person will be seriously impaired unless immediate action is taken and no other person appears to have authority to act. The appointment of a special guardian lasts between ten (10) days and thirty (30) days.

The petition for appointment of a special guardian must be verified. The request may be included in a petition for appointment of a general guardian. This would quickly provide a person to consent to treatment while notice is being given in anticipation of the appointment of a general guardian. Ordinarily, the court will issue a notice of hearing on the petition, which will be set within 72 hours after the filing of the petition. Notice must be served on the subject of the proceeding, his or her attorney, his or her spouse and at least one other adult relative as directed by the court.

The court may, *without any notice,* appoint a special guardian upon the filing of a petition and upon a showing that an immediate or reasonably foreseeable serious physical harm to the subject of the proceeding will result from any delay. If a special guardian is appointed in this manner, the court will serve a copy of the petition, order, and letters of special guardianship on the subject of the proceeding, his or her spouse, and at least one other adult relative of the subject of the proceeding, if the relative is known or can be ascertained with reasonable diligence.

The court will grant the special guardian only those powers necessary to act with respect to the particular emergency, as the court deems necessary. The letters for a special guardian state that the person is a special guardian, the date of the expiration of the special guardianship, and the specific power or powers of the spe-

cial guardian. The appointment of a special guardian is effective from the date of the appointment until a permanent guardian is appointed or for up to thirty (30) days as directed by the court. If the appointment of a special guardian is over the person of the ward only, the court does not require a bond to be filed. At the end of the special guardianship, the special guardian must file a report with the court showing the action taken during the special guardianship.

Consent for Treatment by Guardians

After a guardian or special guardian is appointed, that person may execute waivers or consents for the ward as authorized by the court. In order to make such consents or waivers legally effective, there must be attached to each waiver or consent a certified copy of the court document authorizing the guardian to perform that act.

Protective Services for the Elderly and for Incapacitated Adults Act

The mental health laws of Oklahoma provide for voluntary protective services for an elderly person or incapacitated adult.* These services are provided by the Department of Human Services and include services necessary to help meet the person's essential requirements for health and safety. If an elderly person or incapacitated adult does not consent to the receipt of protective services or if the person withdraws his or her consent and does not appear to be competent to make such a decision, the Department may seek court authorization to provide services.

Emergency protective services may be obtained if the Department of Human Services determines that an elderly person or an incapacitated adult is suffering from such abuse or neglect that there is an immediate and serious risk of physical harm to his/herself or he/she lacks the mental capacity to consent to receive protective services and no consent can be obtained. In such an instance, the Department will petition the court for an emergency order authorizing the protective services. In issuing an emergency order, the court will only authorize the protective services as are necessary to remove the conditions creating the emergency, and the court will specifically designate approved services in its order. Emergency protective services may be provided for a period not to exceed ten (10) calendar days and may be renewed one time. This is frequently the least expensive alternative for the hospital and the patient when an incompetent person needs medical treatment and does not have a guardian. Usually, the hospital social worker is assigned to contact the Department of Human Services to initiate this process.

Services for Children

Parents are the natural legal guardians for children who are under 18 years old. If a parent fails to provide necessary medical care or if there are no known relatives available, the Department of Human Services may be contacted to provide assistance for a "child in need of treatment." These services are also frequently arranged by a hospital social worker.

Conclusion

Family members who need a long-term solution to the problem of handling medical and financial affairs for an incompetent adult should be encouraged to contact an attorney to initiate guardianship proceedings. If a patient is incapable of giving consent to treatment and the incapacity may not be permanent, a special guardianship can take care of the immediate needs of the patient and is less burdensome and expensive for the family. However, this also requires the family to contact an attorney. Families who meet certain income and need guidelines may qualify for assistance through Legal Aid of Eastern or Western Oklahoma.

The least expensive alternative is to contact a social worker who can obtain protective services for the patient under the Protective Services for the Elderly and for Incapacitated Adults Act. This method can also be used for patients who have no known family members and do not require anyone to hire an attorney.

The Author

Teresa Meinders Burkett is an attorney with the Tulsa law firm of Boone, Smith, Davis, Hurst & Dickman.

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Managed care gets attention at OSMA Board of Trustees meeting

The Oklahoma State Medical Association's Board of Trustees convened its quarterly meeting August 22 at OSMA headquarters in Oklahoma City.

Among the first items of business was the presentation of a plaque of appreciation to Lofty L. Basta, MD, Tulsa, who has chaired the OSMA Accreditation Committee. Dr. Basta is leaving the state to pursue new opportunities in Florida.

The remainder of the meeting moved quickly, thanks to a new approach introduced by Chairman of the Board Douglas C. Hubner, MD. Trustees, based on information received in their handbooks, were asked to vote their approval or disapproval of agenda items by mail ballot prior to the meeting. A number of routine items, such as the previous meeting's minutes, OSMA Auxiliary report, PLICO report, and various council and committee reports were approved in this manner. Also approved was Life Membership status for Craig S. Jones, MD, Tulsa.

Board actions at the meeting itself included approval of the following items:

- A motion allowing the Concerned Doctors of America (CDA) to use the name of the OSMA as an endorsement of their public education campaign and donating to the CDA one free page of JOURNAL advertising
- An expenditure of up to $10,000 for actuarial studies regarding Health Access Oklahoma
- An expenditure of up to $3,000 for a speaker to present to the board an educational program about managed care
- Solicitation of proposals for a market survey regarding benefits to be included in a managed care program for Oklahoma.

Prior to approval of the managed care items, a recess was called to allow the board, as a committee of the whole, to discuss managed care.

Three regional AMA meetings to expand two-way communications

Plans for three regional AMA-sponsored meetings, titled "The AMA Brings Washington to You," have been announced by AMA President Joseph T. Painter, MD.

The goal of the fall meetings, to be held in San Francisco, Dallas, and Philadelphia, will give physicians insight into the political atmosphere as Congress begins consideration of Clinton's health care reform proposal.

"Given the stimulus for reform or change in the health delivery system, it is overwhelmingly important for the profession to be united in understanding of goals and objectives, as well as aware of and supportive of the actions being taken on behalf of the profession by its leadership," Dr. Painter said.

Clinton administration officials, members of Congress, and other key players in system reform will take part in each meeting. The meetings are being designed to build on the success of the AMA's Washington event, "A Time for New Partnership," in March.

"We were delighted with the response to the Washington meeting from physicians throughout the country," said Dr. Painter.

"We were particularly impressed by how many of the participants were not formally involved in organized medicine, but literally physicians from 'back home.' These three regional meetings will enable us to reach out to even more physicians and involve them in the health policy arena," he added.

Regional meeting dates and locations are: October 22-24, San Francisco; November 4-6, Dallas; and November 19-21, Philadelphia.

Each meeting will begin with an optional reception

AMA's regional meetings *(continued)*

on the evening of the first day. The second day will include a full day of programming.

The third day will feature three optional seminars from 8 AM to noon. Topics will be: "When 60 Minutes Comes Knocking," a media preparation program for physicians; "Medicine's Candidate: Prescription for Political Success," a seminar to teach physicians how to become politically involved; and "Medicine in Transition: Strategies for Change," a program featuring impending changes in the health care system.

The fee for each meeting, which includes food service, is $50 for AMA members and $125 for nonmembers. For additional information or to register, call 1-800-621-8335.

OU schedules annual critical care medicine course for spring

The 21st Annual Critical Care Medicine Course, to be held March 5-10, 1994, at the Oklahoma City Marriott Hotel, will be an intensive five-day educational experience featuring didactic presentations and workshops.

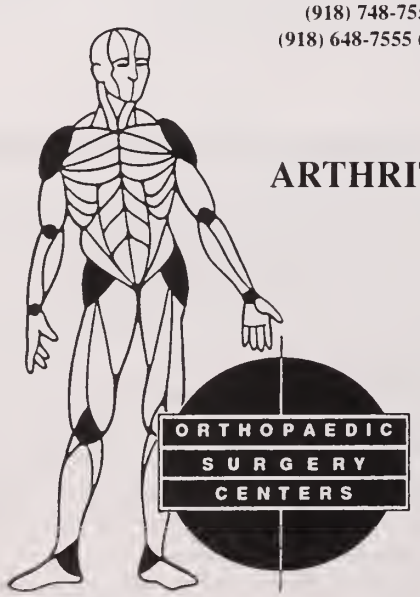
The curriculum will be directed toward physicians who wish to expand their knowledge and improve skills in the field of critical care medicine. The course will provide a review of current and newly accepted procedures as well as investigate new technological developments. It will provide an opportunity for extensive interaction and discussion between registrants and faculty and a forum for multi-disciplinary exchange of information.

Guest speakers will include nationally known physicians Dennis G. Maki, MD, infectious diseases, University of Wisconsin Medical School; Gordon H. Williams, MD, endocrinology and hypertension, Harvard Medical School; John M. Luce, MD, pulmonology/anesthesiology, University of California at San Francisco; and L. David Hillis, MD, cardiology, University of Texas Southwestern Medical Center.

The course will be presented and sponsored by the Department of Medicine, College of Medicine, University of Oklahoma Health Sciences Center, and the Veterans Affairs Medical Center in conjunction with the OUHSC Office of Continuing Medical Education. Pro-

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Critical care course *(continued)*

gram co-directors are Paul V. Carlile, MD, and Martin H. Welch, MD. Tuition is $675 (house staff/allied health $525). Accreditation of 49 hours has been approved by the AMA, AAFP, AOA, and ACEP.

For further information, please contact Dora Lee Smith, Course Coordinator, at (405) 271-5904 or write to: Critical Care Medicine Course, University of Oklahoma Health Sciences Center, Room 3SP-400, P.O. Box 26901, Oklahoma City, OK 73190.

Health Department

Supplemental food program aids women, infants, and children

Focusing on anemia and low birth weight as significant medical problems, the federally funded Supplemental Food and Nutrition Education Program for Women, Infants & Children (WIC) is worth the effort put forth by the Oklahoma medical community.

Reports published in the *Journal of the American Medical Association* of earlier research by Dr. David Rush of the Research Triangle Institute and the Centers for Disease Control in Atlanta continue to confirm the benefits of the WIC program.

The greatest dietary benefits were among people in the highest risk categories: minority women, women with less education, and children who are very poor, short for age, black, or in female-headed families. The Oklahoma State Department of Health believes that in addition to reducing the chances of low birth weight births and the percent of anemic children, WIC clients are also more likely to seek medical care on a regular basis.

Low birth weight (weighing less than five pounds, eight ounces or 2500 grams at birth) is a major infant health problem in the United States. In 1990, the most recent year for which data are available, the proportion of babies born at low birth weight in the United States was 7.0 percent. Oklahoma had 6.5 percent low birth weight babies born in that same year. That translated into 3,093 low birth weight babies.

Very low birth weight is a serious infant health problem because the weight of an infant at birth is the most important determinant of its chances of survival and health, growth, and development. Low birth weight babies that survive are at an increased risk of mental retardation, birth defects, growth and developmental problems, visual and hearing defects, delayed speech, autism, cerebral palsy, epilepsy, learning difficulties, and chronic lung problems. Half of all infant deaths are associated with low birth weight.

Maternal risk factors associated with giving birth to a low birth weight baby include, but are not limited to, absent or inadequate prenatal care, poor nutrition status, and poor weight gain during pregnancy. A study conducted by the United States Department of Agriculture and the Food and Nutrition Service has shown that WIC participation during pregnancy has proven to be associated with a lower incidence of infant mortality and savings in Medicaid costs.

Iron deficiency anemia is also among the most prevalent nutrition problems in the United States, especially among young children. This condition affects children at all income levels, but its incidence is higher among poor children. In 1983, approximately 25 percent of Oklahoma children in the WIC program surveyed through Pediatric Nutrition Surveillance, were reported as indicating hematocrit values below the fifth percentile of standard. In 1992, the pediatric survey showed that the percentage of Oklahoma children with low hematocrit values had declined to 11 percent.

Anemia affects a child's ability to learn and interact in a positive manner with his or her educational environmental. It can have a negative effect on behavior, including shortened attention span, irritability, fatigue, and a decreased ability to concentrate.

Anemic children tend to do poorly on vocabulary, reading, mathematical, problem solving, and psychological tests. The development of their motor abilities is delayed, their memory is impaired, and their ability to combat infection is reduced.

A priority of the WIC program is to educate pregnant women on the importance of adequate nutrition throughout their pregnancy, and to ensure that mothers with young children have the basic nutritional knowledge necessary to assure their children's proper nutrition intake.

WIC clients undergo nutrition education and consultation, and are given materials explaining normal maternal and pediatric nutrition before receiving food items such as iron fortified infant formula, cereal, fruit juice high in vitamin C, milk, eggs, and peanut butter. Currently, 67,000 Oklahomans are participating in the WIC program each month.

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Above, bronze dolphins willingly pose for the camera. Right, guests dine in the stands. Far right, youngster learns to feed dolphins.

Aquaticus picnic for students a big hit

First-year medical students and their families enjoyed the second student picnic to be held at the Oklahoma City Zoo's Aquaticus pavilion. The August 20 event, which acquaints new students with organized medicine, its leaders, and one another before fall classes begin in earnest, is sponsored annually by the OSMA. This year some 200 guests dined on traditional picnic fare—hot dogs, hamburgers, and all the trimmings—while dolphins performed in front of the grandstand.





Guest Editorial

Diabetic retinopathy... we can make a difference!

From primary to subspecialty care, all physicians are called on when a patient develops diabetes mellitus. Hypertension, renal failure, cardiovascular disease, infections, visual loss, and nervous system disorders must all be carefully managed. New advances in diagnosis and treatment are published monthly in multiple medical journals making education across specialty lines essential.

The Oklahoma Academy of Ophthalmology has joined the American Academy of Ophthalmology in "Diabetes 2000," a national peer education effort to rapidly communicate clinical research findings among physicians caring for patients with diabetic retinopathy. The aspirational goal of Diabetes 2000 is to eliminate preventable blindness from the ocular complications of diabetes, especially diabetic retinopathy. this letter marks the launch of our campaign in Oklahoma. Our operational goal is to communicate recent advances in the management of diabetic retinopathy by providing coordinated continuing medical education to every medical community in Oklahoma. A ground swell of activity is occurring with local presentations being delivered by the ophthalmologists in individual communities.

Diabetic retinopathy is the leading cause of blindness is working-age Americans and accounts for at least 12% of new cases of blindness every year in the United States.[1] The two major retinal complications of diabetes are macular edema complicating background retinopathy and vitreous hemorrhage and retinal detachment complicating proliferative retinopathy. An estimated 500,000 Americans have diabetic macular edema with a projected incidence of 75,000 new cases each year; 700,000 have proliferative disease with approximately 65,000 new cases occurring each year.[1] Effective treatment is available. Recently completed randomized prospective studies sponsored by the National Institutes of Health have shown that the incidence of visual loss from diabetic retinopathy can be reduced by half with laser photocoagulation.[2,3] Treatment is most effective at an early, often asymptomatic, stage. With a common disease, a high rate of complications and effective treatment, it is essential that all physicians work together to identify, educate, and optimally treat patients.

The Oklahoma Diabetes 2000 project will communicate recent advances in the knowledge of diabetic retinopathy with specific goals for all physicians:

- Enhance skills in fundus examination and familiarity with the stages of diabetic retinopathy.
- Encourage regular fundus examinations for all diabetic patients.

(continued)

Diabetic retinopathy *(continued)*

• Improve awareness of guidelines for referral of diabetic patients to an ophthalmologist.

The peer interaction facilitated by the Oklahoma Diabetes 2000 project will be an opportunity for ophthalmologists to learn of advancement in the total medical care of persons with diabetes. This mutual education will improve our care of diabetic patients which is the ultimate goal of Diabetes 2000. Together, we can do something about diabetic retinopathy.

—Stephen R. Franson, MD
Oklahoma State Coordinator
Diabetes 2000

1. Patz A, Smith RE. The ETDRS and Diabetes 2000. *Ophthalmology* 1991; 98:739-740.
2. Diabetic Retinopathy Study Research Group. Photocoagulation treatment of proliferative diabetic retinopathy: the second report of the Diabetic Retinopathy Study findings. *Ophthalmology* 1978;85:82-106.
3. Early Treatment Diabetic Retinopathy Study Research Group. Early photocoagulation for diabetic retinopathy: ETDRS report number 9. *Ophthalmology* 1991;98:766-785.

LETTERS

General Counsel defends state medical licensure board

"Who steals my purse steals trash:
'Tis something, nothing;
'Twas mine, 'tis his, and has been slave to thousands;
But he that filches from me my good name
Robs me of that which not enriches him
AND MAKES ME POOR INDEED."

Othello, *Act III, Scene 3*

In the August 1993 issue of the Oklahoma State Medical Association JOURNAL, an editorial and a separate commentary were critical of the Oklahoma Board of Medical Licensure and Supervision. Allegations were made that the Board was "pill-counting" and persecuting doctors who simply prescribed what the Board arbitrarily determined was too much medication. It was implied that the Board had grotesquely over-run the rabbit on that issue to the extent that some Oklahoma physicians were afraid of correctly prescribing controlled medications.

Any such notion is false.

As Board General Counsel, my perspective includes the Board's pure legal authority and the Board members' professional philosophy and tendencies.

The Board members perform a difficult (and thankless) function. Protecting public health, safety and welfare is no picnic. As noted in the JOURNAL editorial, it is indeed an "awesome duty." Board members often face evidence of unprofessional conduct by a physician's own acts and omissions.

At all times, Board members express empathy for the physician and patient alike. The Board must balance the evidence and public and physician interests. I have never heard any Board member be gleeful about voting a sanction against a physician's license. There is no contest among Board members to put any number of "scalps" on the lodge pole. But in some cases, where a physician's own conduct is unprofessional, then the Board must impose some sanction in order to protect the public and to preserve the integrity of all physicians.

Specifically, some physicians are charged with excessive prescribing of controlled dangerous substances. The amount of pills prescribed is not the critical issue. Board members do not merely compute numbers and impose sanctions on some kind of sliding scale.

Instead, the problem arises when controlled dangerous substances are prescribed, administered, or dispensed by a physician *without documented medical need.*

Controlled dangerous substances are proper medication. No Board member quibbles about a physician prescribing controlled dangerous substances. However, controlled dangerous substances do carry addictive risks. That is why they are controlled in the first place. Some controlled dangerous substance prescriptions also have a substantial "street value" to members of the drug underworld. Therefore, medical need for such pharmaceutical agents must be documented. Complete, contemporaneous medical records supporting the prescribing of controlled dangerous substances will protect any physician in the event of inquiry.

What Board members sometimes see is evidence showing long-term prescribing of controlled dangerous substances *without documentation of medical need.* Neither the patient's symptoms, nor even perfunctory physical findings (weight, blood pressure, respiration) appear in the doctor's chart. No subjective or objective symptoms are charted. No consults or lab reports appear. In a number of cases there is *no record whatsoever* to document medical need. In cases of that nature, the Board may very well take disciplinary action.

There is no Board propensity toward finding every physician who appears before them "guilty" of unprofessional conduct. The Board members are conscientious in following the evidence presented in each case. The Board members are guided by the facts of the case.

On some occasions, the Board members have reviewed evidence and *not found* any unprofessional conduct by the physician and imposed no sanction.

Any Board decision is appealable directly to the Oklahoma Supreme Court. Several appeals have been lodged over the years. But the Board legal process has *never* been reversed or criticized by the high Court.

All Board members I have met over the years are physicians of the highest integrity. They come from all corners of Oklahoma. They are diligent in carrying out an unpopular task of protecting public health, safety, and welfare. Board members have no special agenda. They receive no compensation for lost income that occurs while they perform Board business. They are public servants in the most honorable, Jeffersonian sense of that phrase. In my experience, the Board members comport themselves in the highest ethical and professional manner.

Finally, the question is raised in the JOURNAL, "Who Will Guard the Guardians Themselves?" This is a fair question. Under Oklahoma law, the Board of Medical Licensure and Supervision has many guards. The public, the Legislature, the Governor, the media, the courts, various special interest groups, the United States and Oklahoma Constitutions all guard the Board. The Board operates in a deliberate system of governmental and legal checks and balances.

All Board meetings are open, public meetings. The Oklahoma Open Meeting Act requires advance notice of every meeting. Advance copies of the Board agenda are available. Board records are open under the Oklahoma Open Records Act.

Any human system can be improved. I do not represent that the Board is perfect in either its process or its product. But the record speaks for itself over the years that the Board has functioned lawfully and in a conscientious manner. Sometimes the Board takes ac-

(continued)

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John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28

1993

Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd Bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
William Niebuhr Weaver, MD	March 20
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Chester Randall Seba, MD	April 4
Edward Cotter Murray, MD	April 9
Eric McLain White, MD	April 23
John Franklin DeJarnette, Jr., MD	May 1
Harold Alwin Smith, MD	May 4
Kenneth Warren Bonham, MD	May 28
John Raymond Stacy, MD	July 6
Carl Davis Osborn, MD	July 11
Mark Royal Johnson, MD	July 12
W. Turner Bynum, MD	July 13
James Dougherty Martin, MD	July 31
Horace Harold Porter, MD	August 15

Licensure board *(continued)*

tion against a physician's license based on the evidence. Those actions have been upheld by the appellate courts and all the other vigilant sentries who monitor the Board's activities.

Criticism or comments on the Board activities are always welcome. Such public dialogue is usually constructive. But criticism of the Board should be based on true facts.

Any physician is welcome to attend any Board meeting. The Board's business is your business.

"Men at some time are masters of their fates;
The fault, dear Brutus, is not in our stars,
BUT IN OURSELVES, THAT WE ARE UNDERLINGS."
Julius Caesar, Act I, Scene 2

—Daniel J. Gamino
General Counsel for the
Oklahoma Board of Medical Licensure
and Supervision
Oklahoma City

Editor's Note: Mr. Gamino notes that this response is personal and that no present or former Board member asked him to respond or participated in this statement.

Deaths

James Dougherty Martin, MD
1913 - 1993

Retired Cushing general practice physician James D. Martin, MD, died July 31 in Cushing. Dr. Martin was an OSMA Life Member and a 1939 graduate of the University of Oklahoma School of Medicine. After completing a surgery internship in Kansas, he moved to Cushing to join his brother in practice. He served in the U.S. Army from 1942 to 1946 as a captain in neuropsychiatry, before completing his postgraduate studies and returning to Cushing. In 1973 he was appointed Medical Examiner for Payne County. Dr. Martin retired from active practice in 1981.

Horace Harold Porter, MD
1902 - 1993

Horace H. Porter, MD, died August 15, 1993, in Tulsa. Dr. Porter was born in Lexington, Neb., and graduated from the University of Nebraska Medical School in 1929. A general practitioner, he served in the U.S. Navy during World War II, attaining the rank of lieutenant commander. Dr. Porter practiced medicine in Tulsa for more than 40 years before retiring in 1969. He was awarded Life Membership status in the OSMA the same year and in 1971 was named Tulsa's Doctor of the Year.

Classifieds

Classified ads are 50 cents a word, with a minimum of $25 per ad. A word is one or more characters bounded by spaces. Box numbers will be assigned upon request and will add 6 words to the total. Payment must accompany all submissions. **Orders will NOT be accepted via telephone or fax.** Mail ad with payment to OSMA JOURNAL, 601 Northwest Expressway, Oklahoma City, OK 73118. Deadline is the first of the month preceding the month of publication.

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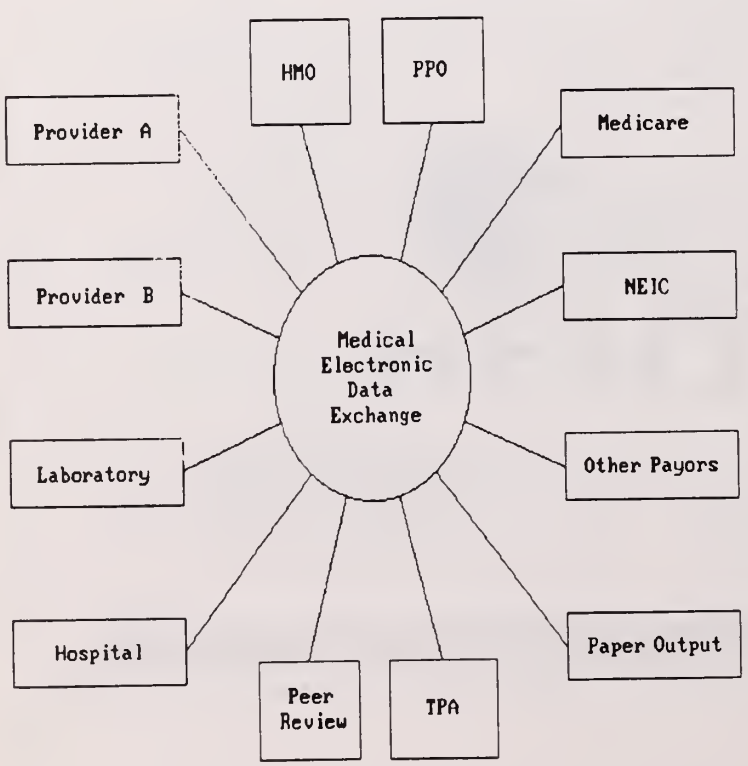
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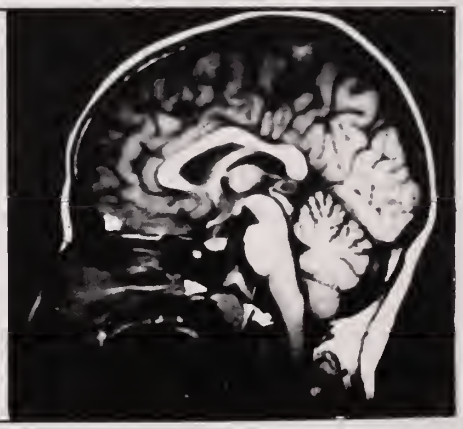
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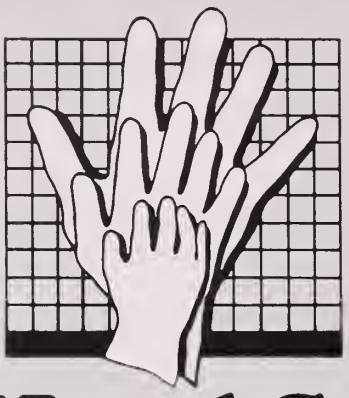
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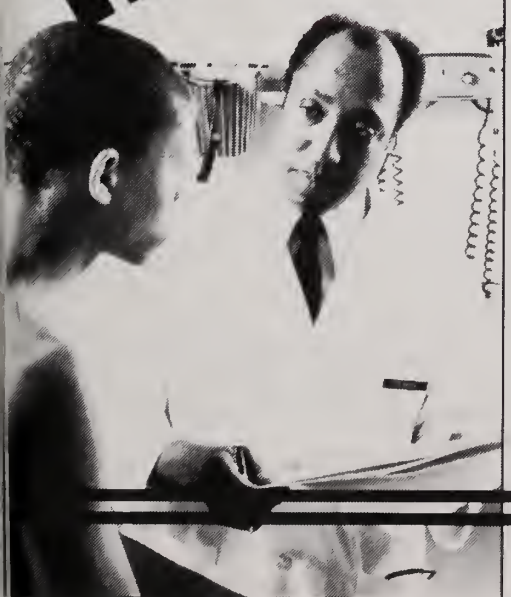
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Style

All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style*. An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

Illustrations

Illustrations other than the author's will not be accepted for publication unless accompanied by written permission from the original source. Illustrations should be labeled with the author's name and must be numbered in the order in which they are referred to in the article. The quality of all illustrations must be in keeping with the quality of the magazine.

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I've Paid My dues

I'VE PAID MY DUES—past tense—a cliché used by many to denote their past efforts were many and they don't need to be involved anymore. I'VE PAID MY DUES—active tense—to say: "I'm now part of the membership teams!"

Recruiting and retaining members is a big responsibility and each of us needs to share in that responsibility. The more people working in the program, the more varied the ideas, the skills, the approaches, and the perspectives will be.

To join the OSMA Auxiliary, one must be the spouse of a physician who is a member of the OSMA. Upon joining a county auxiliary in Oklahoma, dues are automatically shared with the Oklahoma State Medical Association Auxiliary and the American Medical Association Alliance, enrolling each member in all three levels of membership. In counties where there is no organized county auxiliary, a spouse may join as a member-at-large.

What are the benefits of belonging to the national, state, and county medical organizations? They are groups with objectives. Membership offers opportunities for personal growth, community involvement, legislative action, and support for the medical family and its special concerns. You can learn of the services of the organization through *Facets,* the national magazine for and about physicians' spouses. Publications, booklets, audio cassettes, and video cassettes on medical concerns are available from the national alliance and county auxiliaries. Through meeting attendance, contacts, and companionship, friendships and support groups are formed. Social and recreational features highlight many activities. Groups gather to work on mutual problems in the medical and civic communities.

Personal recognition is available through worthwhile service to others. Medical communities throughout Oklahoma develop and staff projects to educate people about the need to improve and maintain good health practices. Each member helps strengthen the bond between his or her spouse's job and the county, state, and national organizations. Your dues help influence legislation through the use of informed people who can see through the smoke screen of Washington politics and what effects certain legislation will have on the medical community, and how you can implement or deter certain issues.

Fund raising for medical education and research is a vital reason for your membership. Well educated physicians and superior research come out of highly funded medical schools. If money is not available, the quality of education and research suffer. Special VISA Card privileges, insurance programs, discounts on hotel rooms and rental cars, and investment services are also privileges of membership.

The Oklahoma State Medical Association Auxiliary needs you to share your talents and knowledge with others, to be involved in your community's health needs, and to add the strength of your voice on health issues. Think of what we can offer you and you can offer others. Then think about joining us. We really can do more together. I hope your response will be: "I've paid my dues!"

For membership information, call Judy Lake at the OSMA offices, 405-843-9571.

—"K" Caldwell
First Vice-President, OSMAA

The Last Word

■ **The fourth edition of *Guides to the Evaluation*** *of Permanent Impairment* is now available from the American Medical Association. The newest edition offers broader criteria for evaluating impairments of the spine and lower extremities and includes a chapter on pain evaluation. There also are new illustrations and charts to help evaluate multiple body systems. Cost to members is $40; nonmembers $60. Call 1-800-621-8335 and ask for OP025493CU.

■ **By now all OSMA members should have received** a copy of the 1993 Legislative Summary prepared by Claudia Kamas, OSMA's director of state legislative affairs. The 12-page report details all medical-related issues considered by the state legislature prior to their adjournment for the summer.

■ **Abstracts of papers on physician health topics** are now being accepted for the International Conference on Physician Health, September 16-20, 1994, in Ottawa, Canada. (Note this is a *new* date. The one announced in last month's JOURNAL was changed because of a scheduling conflict.) The conference has been titled "Stress: The Profession, the Family, and You." Possible topics could include HIV, aging, mental illness, substance abuse, physical disabilities, and limitations caused by general medical conditions. Three types of presentations are invited—poster presentations, paper sessions, and workshops. Abstracts may not exceed 200 words. Submission deadline is February 1, 1994. Contact Elaine M. Tejcek, Physicians Health Foundation, AMA, 1-800-262-3211, ext. 5073.

■ **Rick Ernest, former OSMA associate executive** director, has been name to head the Physician Manpower Training Commission. Ernest formerly held PMTC's number two post behind Don Leavitt, who recently retired.

■ **On August 30, Andrew A. Lasser, chief executive** officer of the University Hospitals in Oklahoma City, announced his intention to resign. CEO since May 1988, Lasser said his decision to step down was made with the best interests of the hospitals in mind; it will allow the University Hospitals Authority to select their own management team to help them move in a new direction. Dr. Jay Stein, provost and senior vice president of the OU Health Sciences Center, said Lasser was a "valuable player" on the health center campus and would be missed.

■ **Medicare pay disparities to new physicians** will end January 1, 1994, as a result of the Omnibus Budget Reconciliation Act of 1993. The AMA and AMA Young Physicians Section worked for years in support of this grass roots initiative. The new law includes estimated Medicare updates (surgery 8.6%, primary care 6.6%, other 4.0%), restoration of full pay for EKGs, full pay for new physicians, and a more reasonable adjustment in practice cost estimates.

■ **Dr. B. Hill Britton has rejoined the faculty of** the Department of Otorhinolaryngology at the University of Oklahoma Health Sciences Center in Oklahoma City. His appointment as associate professor of otology/neuro-otology became effective August 2. Dr. Britton previously served as associate professor in the department from 1988 through 1991 and has been in private practice since that time.

■ **Total medical liability premiums for hospitals** and physicians contributed $9.2 billion to the cost of health care in 1991, according to the Coalition for Effective National Medical Liability Reform. Defensive medicine is estimated to have contributed another $25 billion. Physician liability premiums nearly tripled in the last decade and were the fastest growing component of practice expenses during that decade, says the coalition.

Coalition members include such organizations as the American Medical Association, the Physician Insurers Association of America, and the Pharmaceutical Manufacturers Association. The newly formed group will work to gain public and Congressional support for meaningful medical liability reform. It hopes to communicate the inadequacy of the current liability system and demonstrate that it increases health care costs, reduces access to care, and damages the physician/patient relationship.

■ **Ted Clemens, Jr., MD, Oklahoma City hema**tologist/oncologist, has been named medical director for Aetna Medicare. He succeeds the late Mark R. Johnson, MD. Dr. Clemens was medical director at Presbyterian Hospital for 16 years. ▯

Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhebdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life (t1/2) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro*, with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli*, a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae*. In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area ($mg/meter^2$). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy, this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

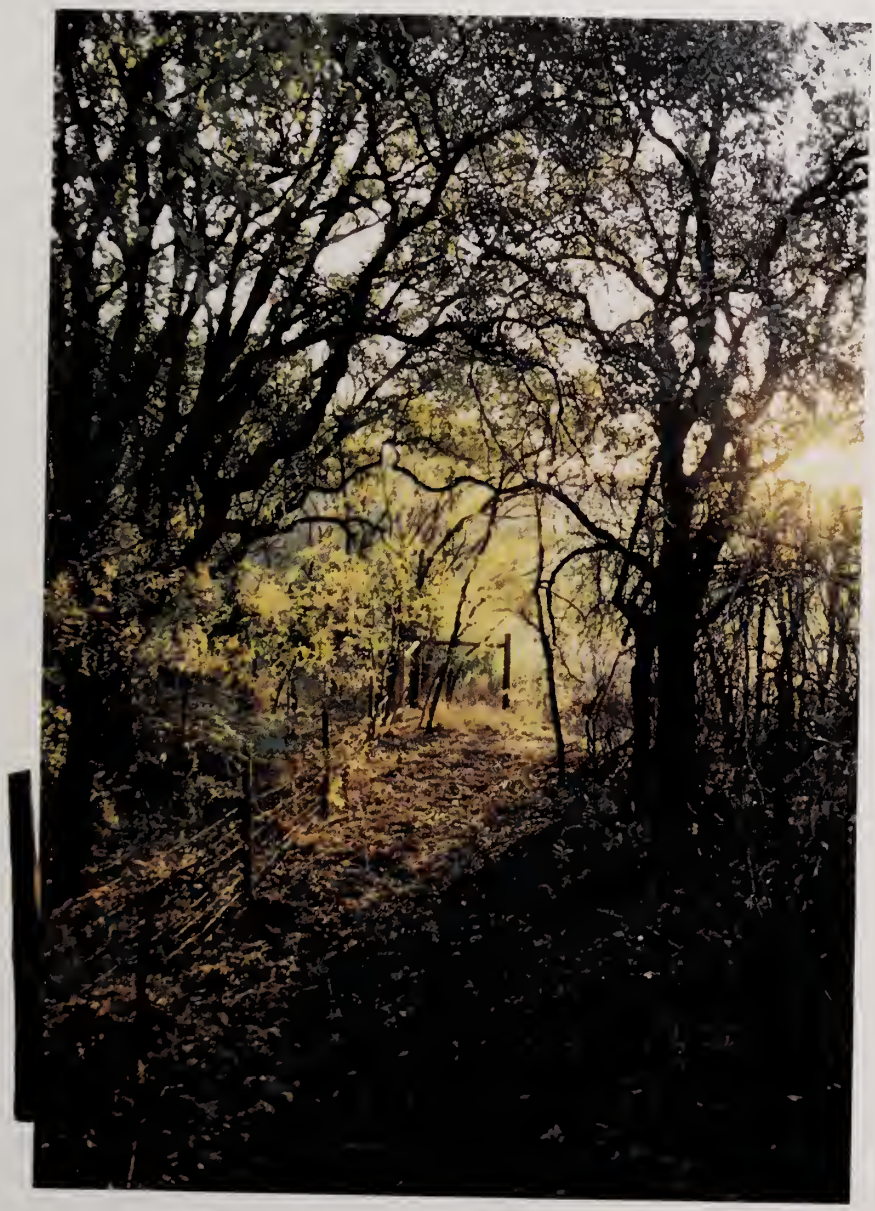
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bone marrow assay

Enalapril Maleate: There was no evidence of a tumorigenic effect when enalapril was administered for 106 weeks to rats at doses up to 90 mg/kg/day (150 times* the maximum daily human dose). Enalapril has also been administered for 94 weeks to male and female mice at doses up to 90 and 180 mg/kg/day, respectively, (150 and 300 times* the maximum daily dose for humans) and showed no evidence of carcinogenicity

Neither enalapril maleate nor the active diacid was mutagenic in the Ames microbial mutagen test with or without metabolic activation. Enalapril was also negative in the following genotoxicity studies: rec-assay, reverse mutation assay with *E. coli*, sister chromatid exchange with cultured mammalian cells, and the micronucleus test with mice, as well as in an *in vivo* cytogenic study using mouse bone marrow

There were no adverse effects on reproductive performance in male and female rats treated with 10 to 90 mg/kg/day of enalapril.

Hydrochlorothiazide: Two-year feeding studies in mice and rats conducted under the auspices of the National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of up to approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepatocarcinogenicity in male mice.

Hydrochlorothiazide was not genotoxic *in vitro* in the Ames mutagenicity assay of *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or *in vivo* in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the *Drosophila* sex-linked recessive lethal trait gene. Positive test results were obtained only in the *in vitro* CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell (mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 µg/mL, and in the *Aspergillus nidulans* non-disjunction assay at an unspecified concentration.

Hydrochlorothiazide had no adverse effects on the fertility of mice and rats of either sex in studies wherein these species were exposed, via their diet, to doses of up to 100 and 4 mg/kg, respectively, prior to conception and throughout gestation.

Pregnancy: Pregnancy Categories C (first trimester) *and D* (second and third trimesters). See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Nursing Mothers: Enalapril and enalaprilat are detected in human milk in trace amounts. Thiazides do appear in human milk. Because of the potential for serious reactions in nursing infants from either drug, a decision should be made whether to discontinue nursing or to discontinue VASERETIC, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: VASERETIC has been evaluated for safety in more than 1500 patients, including over 300 patients treated for one year or more. In clinical trials with VASERETIC no adverse experiences peculiar to this combination drug have been observed. Adverse experiences that have occurred, have been limited to those that have been previously reported with enalapril or hydrochlorothiazide.

The most frequent clinical adverse experiences in controlled trials were: dizziness (8.6 percent), headache (5.5 percent), fatigue (3.9 percent) and cough (3.5 percent). Adverse experiences occurring in greater than two percent of patients treated with VASERETIC in controlled clinical trials were: muscle cramps (2.7 percent), nausea (2.5 percent), asthenia (2.4 percent), orthostatic effects (2.3 percent), impotence (2.2 percent), and diarrhea (2.1 percent).

Clinical adverse experiences occurring in 0.5 to 2.0 percent of patients in controlled trials included: *Body As A Whole:* Syncope, chest pain, abdominal pain; *Cardiovascular:* Orthostatic hypotension, palpitation, tachycardia; *Digestive:* Vomiting, dyspepsia, constipation, flatulence, dry mouth; *Nervous/Psychiatric:* Insomnia, nervousness, paresthesia, somnolence, vertigo; *Skin:* Pruritus, rash; *Other:* Dyspnea, gout, back pain, arthralgia, diaphoresis, decreased libido, tinnitus, urinary tract infection.

Angioedema: Angioedema has been reported in patients receiving VASERETIC (0.6 percent). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with VASERETIC should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

Hypotension: In clinical trials, adverse effects relating to hypotension occurred as follows: hypotension (0.9 percent), orthostatic hypotension (1.5 percent), other orthostatic effects (2.3 percent). In addition syncope occurred in 1.3 percent of patients. (See WARNINGS.)

Cough: See PRECAUTIONS, *Cough.*

Clinical Laboratory Test Findings, Serum Electrolytes. See PRECAUTIONS.

Creatinine, Blood Urea Nitrogen. In controlled clinical trials minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 0.6 percent of patients with essential hypertension treated with VASERETIC. More marked increases have been reported in other enalapril experience. Increases are more likely to occur in patients with renal artery stenosis. (See PRECAUTIONS.)

Serum Uric Acid, Glucose, Magnesium, and Calcium: See PRECAUTIONS.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.3 g percent and 1.0 vol percent, respectively) occur frequently in hypertensive patients treated with VASERETIC but are rarely of clinical importance unless another cause of anemia coexists. In clinical trials, less than 0.1 percent of patients discontinued therapy due to anemia.

Liver Function Tests. Rarely, elevations of liver enzymes and/or serum bilirubin have occurred.

Other adverse reactions that have been reported with the individual components are listed below and, within each category, are in order of decreasing severity.

Enalapril Maleate—Enalapril has been evaluated for safety in more than 10,000 patients. In clinical trials adverse reactions which occurred with enalapril were also seen with VASERETIC. However, since enalapril has been marketed, the following adverse reactions have been reported. *Body As A Whole:* Anaphylactoid reactions (see PRECAUTIONS, *Hemodialysis Patients*); *Cardiovascular:* Cardiac arrest, myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, *Hypotension*); pulmonary embolism and infarction; pulmonary edema; rhythm disturbances including atrial tachycardia and bradycardia; atrial fibrillation; hypotension; angina pectoris; *Digestive:* Ileus, pancreatitis, hepatic failure, hepatitis (hepatocellular [proven on rechallenge] or cholestatic jaundice), melena, anorexia, glossitis, stomatitis, dry mouth; *Hematologic:* Rare cases of neutropenia, thrombocytopenia and bone marrow depression. Hemolytic anemia, including cases of hemolysis in patients with G-6-PD deficiency, has been reported, a causal relationship to enalapril has not been established. *Nervous System/Psychiatric:* Depression, confusion, ataxia, peripheral neuropathy (e.g., paresthesia, dysesthesia); *Urogenital:* Renal failure, oliguria, renal dysfunction (see PRECAUTIONS), flank pain, gynecomastia; *Respiratory:* Pulmonary infiltrates, bronchospasm, pneumonia, bronchitis, rhinorrhea, sore throat and hoarseness, asthma, upper respiratory infection; *Skin:* Exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, herpes zoster, erythema multiforme, urticaria, pemphigus, alopecia, flushing, photosensitivity; *Special Senses:* Blurred vision, taste alteration, anosmia, conjunctivitis, dry eyes, tearing.

Miscellaneous: A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia/myositis, fever, serositis, vasculitis, leukocytosis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Fetal/Neonatal Morbidity and Mortality: See WARNINGS, *Pregnancy, Enalapril Maleate, Fetal/Neonatal Morbidity and Mortality.*

Hydrochlorothiazide—Body as a Whole: Weakness; *Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), sialadenitis, cramping, gastric irritation, anorexia; *Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia, *Hypersensitivity:* Purpura, photosensitivity, urticaria, necrotizing angiitis (vasculitis and cutaneous vasculitis), fever, respiratory distress including pneumonitis and pulmonary edema, anaphylactic reactions; *Musculoskeletal:* Muscle spasm; *Nervous System/Psychiatric:* Restlessness; *Renal:* Renal failure, renal dysfunction, interstitial nephritis (see WARNINGS); *Skin:* Erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia; *Special Senses:* Transient blurred vision, xanthopsia.

* Based on patient weight of 50 kg

For more detailed information, consult your DuPont Pharma Representative or see Prescribing Information.

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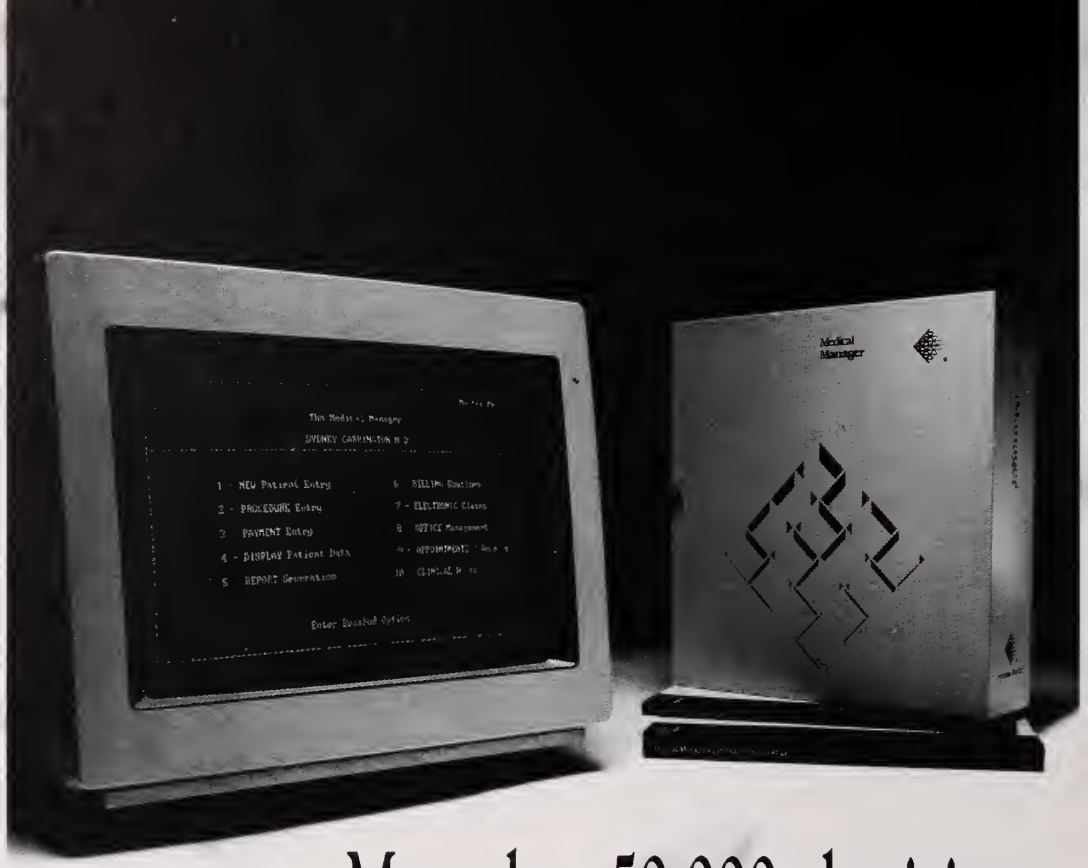


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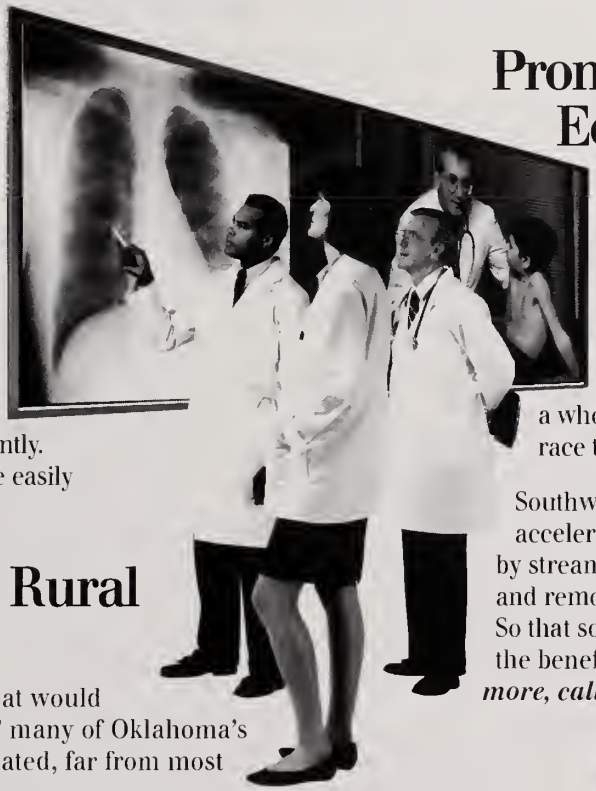
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Ray V. McIntyre, MD

Health Access Oklahoma

There is a season to sow and a season to reap, according to the ancient tribal wisdom, and thirty years of government mandates on health care have now irretrievably changed how health care is paid for in America. As a result, the physician/patient relationship is changing alarmingly. Now, non-medical actuaries devoid of altruism are the gatekeepers of medical care. The season is here for a necessary change in the contract between government, patient, and physician.

The OSMA Board of Trustees recognizes this season of change has arrived and has initiated Health Access Oklahoma to make Oklahoma physicians positive players in the game about to be played.

The exact goal in this game is as yet unidentified, and will be influenced by the final form of health care reform legislation now being generated in Washington, and by the actions of the Oklahoma

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Legislature. The principal thrust of the OSMA initiative is to form a medical insurance company including all willing physicians in Oklahoma and then offer a defined benefits package of medical care to insured groups.

This is obviously a risky undertaking involving dollars of capitalization and a commitment of individual physician time and energy put to learning a new, non-medical skill—the management of a medical insurance company. The OSMA experience with PLICO Health provides a positive nucleus of knowledge and personnel, even though a "statewide provider network" insurance operation would have new and larger problems. But to succeed like PLICO, physician decision-making that is based on good medical and actuarial knowledge must be widely effective in the new project. A lot of physician time must be zealously committed.

A not-for-profit physicians insurance company will be much better accepted by the public, the politicians, and the business community. The public generally thinks physicians' fees are already too high, and to profit from a medical insurance operation would be generally unacceptable. Those physicians whose time will make the new company work should be paid at a reasonable rate, but all physicians need to come to think that the principal benefit of Health Access Oklahoma is the opportunity to recover medical decision-making from the insurance industry.

Fifty years ago the Blue Cross movement was invented and launched by physicians, and was a force for good in our society for a time. But then the decisive posts were taken over by insurance people, bankers, "consumers," and labor representatives, and soon Blue Cross was just another insurance company that was part of the problem instead of part of the solution. An OSMA "statewide provider network" must guard assiduously against such a fate.

There may be major political tides running against physician benefit from initiatives such as Health Access Oklahoma. But there also is general awareness that the main elements of modern medical care can be delivered only by physicians. Thus the physician group that presents a united front and a positive program that tackles society's medical problems is a powerful force.

The season of change is at hand; let us sow the seeds of a medical care system where medical decisions are made by physicians only. Let's go for it!

Ray V. McIntyre, M.D.

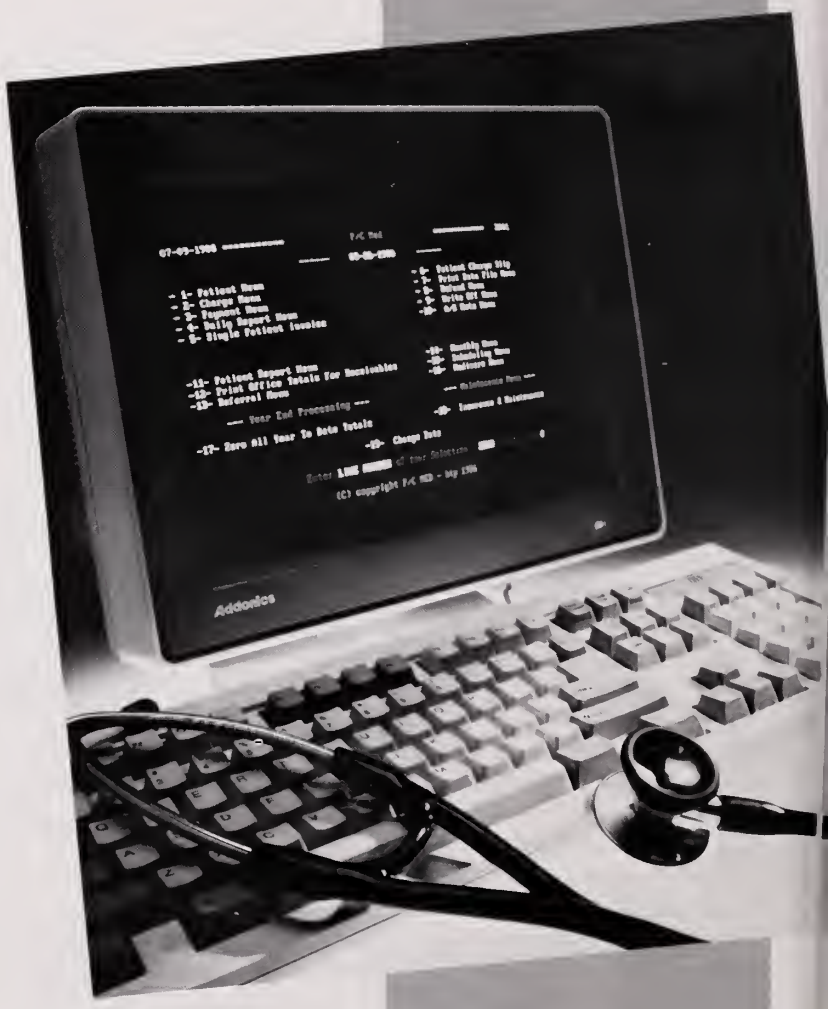
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PRESIDENT'S PAGE

G. Lance Miller, MD

A Primer for Involvement



Several weeks ago a very important meeting was held at OSMA headquarters in Oklahoma City. For the first time in many years, specialty society presidents were invited to meet with the Oklahoma State Medical Association president and president-elect.

It is clear as we enter this new era of health system reform that the worst thing that can happen to the House of Medicine is for it to become splintered with physicians pitted against each other because of specialty-specific interests. This will play right into the hands of those who would control us.

I am pleased to report that the meeting was extremely productive. We all laid our cards on the table. Criticisms and misconceptions—big and small, old and new—were discussed in a frank but conciliatory and collegial manner. The gathering was so worthwhile that the specialty society presidents recommended quarterly meetings in the future.

Recently, when responding to a question from an Oklahoma City television reporter on how he, as a specialist, would be affected by President Clinton's health care reform plan, Oklahoma County Medical Society President Roland A. Walters, MD, said: "I am a physician first and then a specialist, and like all physicians I worry how the President's plan will affect my patients."

These are words for all of us to remember.

One of the main misconceptions, I thought, of the specialty society presidents also pertains to individual physicians. There was a recurring theme among the presidents that the OSMA was too big to address the needs of their particular specialties. I know many individual physicians who feel this way about the OSMA and, especially, the American Medical Association.

Yes, the OSMA is a big organization with some 4,700 members. But it also is as small as its Board of Trustees and officers.

Yes, the AMA is a big organization with some 300,000 members. But it also is as small as the fourteen-member Oklahoma AMA Delegation.

Your officers, trustees, and AMA delegates are your friends and colleagues. They are only a phone call away. I assure you they all take their positions very seriously and seek your ideas and input. If you dislike—or perhaps even like—something the OSMA or AMA is or isn't doing, let them know.

Better yet, in these crucial times for our profession, get involved by becoming an active member of your county medical society, the very heart and soul of organized medicine. Spread medicine's message in your own community. Become a delegate to the OSMA where your voice can be heard at the state level.

While the OSMA and AMA appear to be big organizations, in reality they are as small as you and I and will be only as effective as the work you and I do for them—and for us.

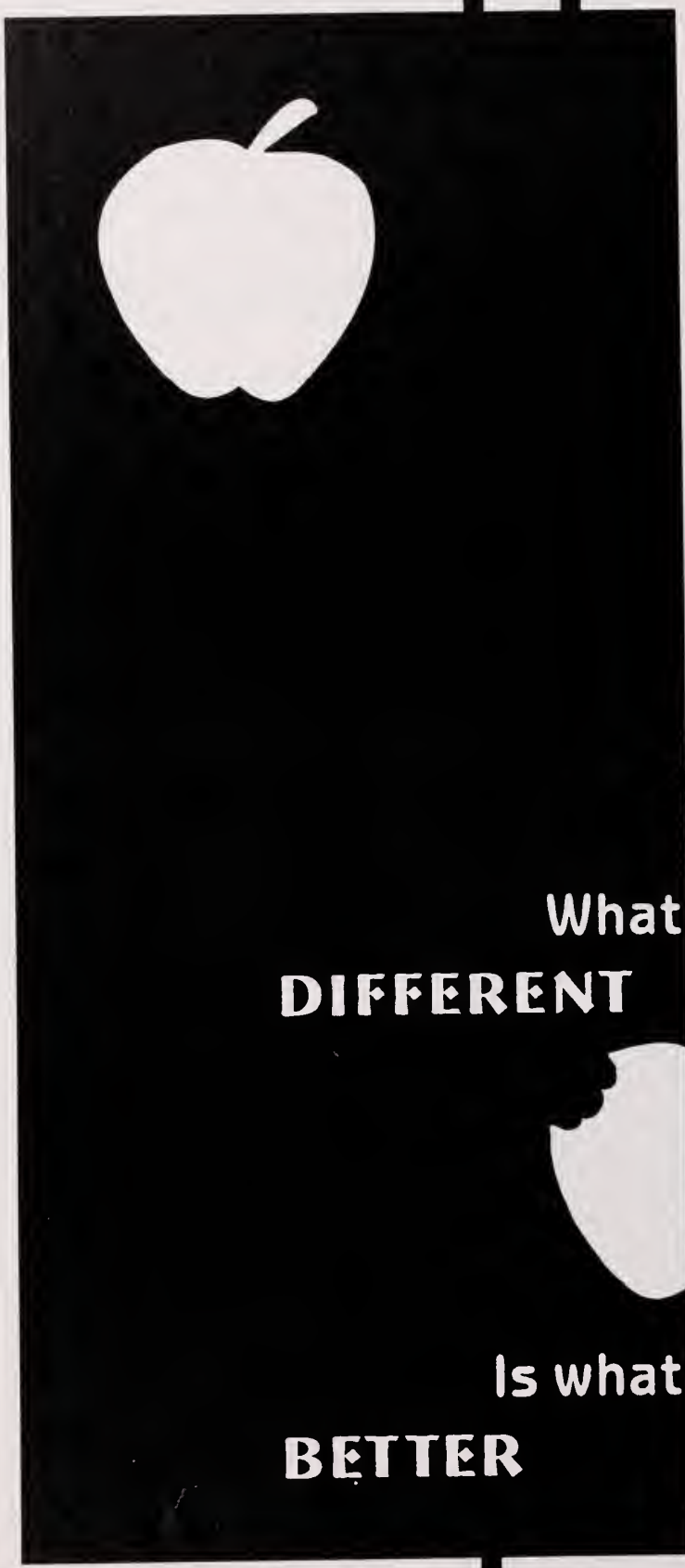
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HEAL

Pneumococcal Septicemia and Pneumonia in the Neonatal Period

Mary Anne McCaffree, MD; Harris D. Riley, Jr., MD

Infections due to *Streptococcus pneumoniae* are extremely rare in the neonatal period. A newly born infant with pneumococcal septicemia and pneumonia is described.

INFECTION DUE TO *STREPTOCOCCUS PNEUMONIAE* IN the neonatal period is quite rare. Only an occasional case has been reported. The mortality in the sporadic cases reported has been high, particularly in early onset disease. Moreover, there is evidence that pneumococcal infections in the newly born infant may be increasing in frequency.[1,2]

The purpose of this article is to report a case of pneumococcal septicemia and pneumonia occurring in a neonate with survival of the infant.

Case Report

E.O. (No. 88-54-41-2), a white male infant, at 37 hours of age, was transferred to the Neonatal Intensive Care Unit, Children's Hospital of Oklahoma, from a community hospital because of respiratory distress and an abnormal chest radiograph. The infant had been delivered at 35 weeks gestation by vaginal vertex delivery after 25 hours of spontaneous membrane rupture to a 26-year-old gravida 4, para 3. Birth weight was 2,600 grams. The mother's pregnancy was complicated by threatened preterm delivery and she was placed on ritodrine hydrochloride one month prior to delivery. The mother had no history of respiratory or other infections in the period immediately before delivery; there was no clinical evidence of vaginal or uterine infection. Maternal genital cultures were not taken. The infant's Apgar scores at the referring hospital were 8 and 9 at one and five minutes respectively. The physical examination immediately following birth revealed no abnormalities. Initially his condition was stable but he developed hypoglycemia (glucose concentration 30 mg/ml) within a few hours of birth and was given early oral feedings of glucose. At 16 hours of age he became tachypneic and shortly thereafter developed bradycardia, apnea, and an elevated temperature (100.6°F). The hemoglobin concentration at birth was 12 gm/100 ml, and over the next few hours it progressively diminished to 8.9 gm/100 ml. The infant demonstrated an increasing leukopenia with the leukocyte count falling from 4,300/cmm to 1,600/cmm. The differential count revealed only 4 neutrophilic forms. A chest radiograph revealed right middle and lower lobe infiltrates. An evaluation for sepsis including blood, urine, and cerebrospinal fluid cultures was carried out at 28 hours of age, and empiric therapy with ampicillin and gentamicin administered intravenously was begun.

The infant was transferred by air transportation in 50% oxygen concentration delivered by hood; his vital signs remained stable. Upon arrival the infant exhibited apnea and poor peripheral perfusion. The examination was otherwise not remarkable. He was intubated and placed on mechanical ventilation. On the day following admission, the laboratory of the referring hospital reported that the culture of the placenta and the blood culture from the infant both yielded *Streptococ-*

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cus pneumoniae. In vitro susceptibilities of the strain isolated from the placenta were subsequently reported and revealed the organism to be susceptible to ampicillin, penicillin G, and various cephalosporins. Gentamicin was discontinued, ampicillin was continued for a few hours, and penicillin G therapy was initiated. Blood cultures obtained at the time of admission to Children's Hospital of Oklahoma were subsequently reported as negative but the bacterial antigen tests of the urine were positive for *S. pneumoniae.* Cultures from the endotracheal tube yielded this organism. These findings supported the diagnosis of pneumococcal septicemia and pneumonia.

The infant received transfusions of packed red blood cells and white blood cells. He also received gamma globulin (500 mg/kg) intravenously. Following this treatment he exhibited progressive clinical improvement. Concomitantly there was progressive clearing of the anemia, leukopenia, and neutropenia.

He was weaned from the ventilator on the fourth hospital day but was still oxygen dependent. The chest radiograph revealed gradual diminution in the pulmonary infiltrates.

At the parents' request, the infant was transferred to the referring hospital on the seventh day of life.

Discussion

The newborn infant appears to have partial protection from invasive disease due to the *Streptococcus pneumoniae*[3]; thus, clinical neonatal pneumococcal infections are rare. Pneumococci are isolated in only about 2% of all cases of neonatal septicemia.[4,5] This organism is found in about 6% of cases of neonatal bacterial meningitis.[6]

If a mother harbors *S. pneumoniae* as part of her vaginal flora, her infant can become infected after premature rupture of the membranes or during birth. The clinical infections most often found have been pneumonia, septicemia, and meningitis.[7]

Bacteria may reach the fetus or infant by four different mechanisms. First, in rare cases the fetus may be infected transplacentally through the mother's blood stream. Second, early-onset infections, which are typical for group-B streptococcal disease, are often a result of premature rupture of the membranes or an invasion of bacteria ascending from the cervix or vagina through intact membranes. Third, infection may occur during the infant's passage through the birth canal. Finally, bacteria may be introduced from the environment.[8]

Despite the reported rarity of pneumococcal infections in the newborn period, Bortolussi and co-workers[7] reported the occurrence within one year of pneumococcal bacteremia in four newborn infants at the University of Minnesota Hospital in Minneapolis. These infants had signs of sepsis within the first 24 hours of life. The same pneumococcal serotype was present in vaginal secretions from three of the mothers; this fact suggested that the organisms were acquired by the infants from the maternal genitalia.

Westh et al[8] reviewed the literature and analyzed 23 reported cases of neonatal pneumococcal infections occurring between 1938 and 1988. At birth the infected infants had a median gestational age of 38 weeks and weighed a median of 2,720 grams. There were slightly more males than females. All infections were of early onset (before the fifth day postpartum); this timing supports the theory of ascending bacteria from the vagina as the source of the infection. Eleven of the 23 infants died, and 3 of the survivors had severe neurologic sequelae. From 1979 to 1988 there was a tendency for increased survival among neonates with pneumococcal infection. When the data on outcome were corrected to reflect the survival of neurologically intact infants, however, this tendency was no longer evident. Rupture of the membranes greater than 24 hours before birth was seen in only 2 of 15 cases, but in 9 instances rupture occurred greater than 12 hours before birth. In all cases but one, pneumococci were isolated from the birth canal. The latter case, in which the mother had meningitis and septicemia, may have been a rare case of transplacental infection, but genital cultures were not performed.

Timing supports the theory of ascending bacteria from the vagina as the source of the infection.

Sporadic cases of neonatal pneumococcal infection have been reported from time to time.[9-12]

In the patient reported here, *S. pneumoniae* was isolated from the placenta, suggesting that infection of the infant occurred transplacentally from the maternal blood stream. This is one of the least common modes of pneumococcal infection of the fetus.

Acknowledgement

Appreciation is expressed to Dr. John E. Provine, Enid, for referring the patient and to Kristi S. Stone and April Lampley for typing the manuscript.

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Incidence of Bacteria from Clean-Catch and Catheterized Urine of Nursing Home Residents

D.J. Flournoy, PhD

Urine cultures from 1990 through 1992 were analyzed to determine the incidence of common isolates in residents from over 50 nursing homes in Oklahoma. Of all 11,480 isolates in clean-catch and catheterized specimens, the most common were: *Escherichia coli* (24% of all isolates), *Pseudomonas aeruginosa* (11%), *Proteus mirabilis* (10%), *Enterococcus faecalis* (8%), *Klebsiella pneumoniae* (7%), *Providencia stuartii* (5%), and *Staphylococcus aureus* (4%). The most striking findings of this study were the similarities in frequencies of isolates from clean-catch and catheterized urines, the common occurrence of *P. stuartii,* and the low proportion of urea-splitting *P. stuartii* isolates from catheterized specimens.

THE PERCENT OF NURSING HOME RESIDENTS WITH bacteriuria ranges from 18 to 28 for women and 6 to 14 for men.[1-3] The most common pathogens include *Escherichia coli, Proteus* sp., *Klebsiella* sp., *Enterobacter* sp., *Serratia* sp., *Pseudomonas aeruginosa, Staphylococcus aureus,* and *Enterococcus faecalis.*[4-13] *E. coli* is reported to cause up to 80% of urinary tract infections in ambulatory elderly men and women, but a lesser proportion in institutionalized patients.[14] Although the etiological agents of urinary tract infection in the elderly have been studied extensively, there is little information comparing the incidence of isolates from clean-catch versus catheterized specimens of nursing home residents. The purpose of this brief study was to establish and compare the incidence of urinary tract isolates from residents of over 50 Oklahoma nursing homes.

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Materials and Methods

Identification testing was performed by a Microscan Walkaway automated instrument (Baxter Healthcare Corp., MicroScan Division, West Sacramento, Calif.) at Langsam Health Services (LHS) Laboratory. LHS is a private laboratory in Oklahoma City which services over 50 nursing homes in Oklahoma. The study was retrospective covering the period from 1990 through 1992.

The Vacutainer Urine C&S Transport Kit for midstream specimens (Becton Dickinson, Rutherford, N.J.) was used for collection of urine specimens. This kit utilized boric acid as an agent to prevent multiplication of microorganisms while preserving viability. The most predominant isolates with colony counts of equal to or greater than 10^4 colony-forming units/ml were worked up for clean-catch specimens, whereas the top three isolates (regardless of colony count) were worked up on catheterized specimens.

Results

Tables 1 and 2 note the frequency of common isolates from clean-catch and catheterized urines, respectively. In addition, *Staphylococcus saprophyticus* was isolated from clean-catch (1990, 1 isolate; 1991, 4; 1992, 0) and catheterized urines (1990, 1; 1991, 3; 1992, 1). Table 3 notes urease production among *Providencia stuartii* isolates.

Discussion

One interesting finding of this study was the common occurrence of *Providencia stuartii* in both catheterized and clean-catch specimens. *P. stuartii* is known to be a persistent[15] pathogen in long-term catheterized patients,[16] presumably due to adherence of organisms to the catheter. When Nordenstam, et. al., screened 1966 healthy non-institutionalized elderly individuals from Sweden (1971-77), they found *Providencia* sp. in only 1.6% of 124 isolates from positive cultures.[10] Another study found *P. stuartii* to represent 6% of isolates in clean-catch specimens from elderly long-term care patients in a Canadian veterans hospital.[17] In institutionalized women with asymptomatic bacteriuria, *Providencia* sp. comprised 1% of the isolates.[18] In this study, *P. stuartii* occurred in 4.3% of the clean-catch and 6.2% of the catheterized specimens. However, our subjects were from nursing homes and many were likely to be non-ambulatory females. The incidence of *P. stuartii* might be higher than noted in some studies since the organism is not readily identified by some commercial laboratories.[19] However, *P. stuartii* was not a common urinary tract isolate from veterans in Oklahoma from 1975 to 1985,[20] a fact which might be more related to long-term than acute care institutions.

Table 1. Clean-Catch Urine Isolates

	% of Isolates for the Year		
Rank	1990	1991	1992
1	*E. coli* (26%)	*E. coli* (28%)	*E. coli* (26%)
2	*P. mirabilis* (11%)	*P. mirabilis* (9%)	*P. mirabilis* (9%)
3	*P. aeruginosa* (10%)	*P. aeruginosa* (9%)	*K. pneumoniae* (8%)
4	*E. faecalis* (8%)	*K. pneumoniae* (7%)	*E. faecalis* (7%)
5	*K. pneumoniae* (7%)	*E. faecalis* (5%)	*P. aeruginosa* (7%)
6	*S. aureus* (4%)	*P. stuartii* (4%)	*P. stuartii* (5%)
7	*P. stuartii* (4%)	*S. aureus* (4%)	*Micrococcus* sp. (4%)
	Others (30%)	Others (29%)	Others (34%)

Totals: 1990 (2561 isolates), 1991 (2419 isolates), 1992 (1191 isolates)

Escherichia coli, Proteus mirabilis, Pseudomonas aeruginosa, Enterococcus faecalis, Klebsiella pneumoniae, Staphylococcus aureus, Providencia stuartii (urease positive and negative isolates combined)

Table 2. Catheterized Urine Isolates

	% of Isolates for the Year		
Rank	1990	1991	1992
1	*E. coli* (21%)	*E. coli* (20%)	*E. coli* (19%)
2	*P. aeruginosa* (13%)	*P. aeruginosa* (14%)	*P. mirabilis* (10%)
3	*P. mirabilis* (10%)	*P. mirabilis* (10%)	*P. aeruginosa* (10%)
4	*E. faecalis* (8%)	*E. faecalis* (8%)	*E. faecalis* (9%)
5	*K. pneumoniae* (8%)	*K. pneumoniae* (6%)	*P. stuartii* (9%)
6	*S. aureus* (5%)	*P. stuartii* (6%)	*K. pneumoniae* (7%)
7	*P. stuartii* (4%)	*S. aureus* (3%)	*S. aureus* (3%)
	Others (31%)	Others (33%)	Others (33%)

Totals: 1990 (1384 isolates), 1991 (2708 isolates), 1992 (1217 isolates)

Escherichia coli, Proteus mirabilis, Pseudomonas aeruginosa, Enterococcus faecalis, Klebsiella pneumoniae, Staphylococcus aureus, Providencia stuartii (urease positive and negative isolates combined)

It has been reported that urea-splitting Gram negative bacilli can be problematic urinary tract pathogens for the elderly.[21] When urea is split by the bacterial enzyme urease, urine is alkalinized. Alkalinized urine promotes crystallization of struvite and apatite, thus causing encrustation and catheter blockage.[22] Urea-splitting organisms include *Proteus mirabilis* and *vulgaris, Providencia rettgeri*, and *Morganella morganii*. However, only about 30% of *Providencia stuartii* isolates split urea.[23] In this study, the percentage of urea-splitting *P. stuartii* was 17% in clean-catch and only 11% in catheterized specimens. The data from this study suggests that the production of urease was not a major factor relating to the incidence of *P. stuartii* in clean-catch or catheterized urines.

Table 3. Comparison of Urease Positive and Negative *Providencia stuartii*

	Number of Isolates (%)			
	Clean-Catch		Catheterized	
Year	Urea+	Urea–	Urea+	Urea–
1990	22 (22%)	80 (78%)	7 (12%)	51 (88%)
1991	19 (18%)	87 (82%)	18 (12%)	146 (88%)
1992	4 (7%)	50 (93%)	10 (10%)	95 (90%)

In summary, the most striking findings of this study were the similarities in frequencies of isolates from clean-catch and catheterized urines, the common occurrence of *P. stuartii*, and the low proportion of urea-splitting *P. stuartii* isolates from catheterized specimens.

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Use of Powers of Attorney in the Health Care Setting

Teresa Meinders Burkett

This article explains the various types of powers of attorney which may be used in the health care setting in Oklahoma. In conjunction with the new Oklahoma Rights of the Terminally Ill or Persistently Unconscious Act, the legislature made significant changes to the statutes governing powers of attorney. The effective date of this new legislation was September 1, 1992.

A POWER OF ATTORNEY IS AN INSTRUMENT WHICH AUthorizes another to act as one's agent or attorney-in-fact, as distinguished from an attorney-at-law. The person who appoints an attorney-in-fact is the principal. As of October 1, 1993, there are two statutory forms of powers of attorney. A power of attorney is also available by common law in Oklahoma. The three types of power of attorney are: (1) Supervised Power of Attorney, (2) Durable Power of Attorney under the Uniform Durable Power of Attorney Act; and (3) Common Law Power of Attorney. The Power of Attorney most frequently encountered in the health care setting is the Durable Power of Attorney.

Supervised Power of Attorney

A supervised power of attorney is a power of attorney by which a person names another to be his or her attorney-in-fact and charges the attorney-in-fact with the care, custody, and management of his or her estate. This type of power of attorney must be approved by the court and is ordinarily executed to manage property rather than the person of the principal. This power of attorney is created by the principal filing a petition with the county court requesting that a certain person be named his or her attorney-in-fact. The holder of the supervised power of attorney must be bonded and notice of the power must be published in a local newspaper and mailed to all relatives of the principal prior to the court's approval of the instrument. The attorney-in-fact created by this method must render an accounting to the court of his or her actions in a manner similar to that required of guardians.

Supervised powers of attorney are very rarely requested or put into effect. Because the supervised power of attorney is ordinarily used for property matters, it is unlikely that the physician's staff will encounter this type of instrument in a health care setting. Also, unless a supervised power of attorney meets the additional requirements for a durable power of attorney, a supervised power of attorney will terminate when the principal becomes incompetent.

Should the physician receive a document entitled *Supervised Power of Attorney,* it should be reviewed to determine whether the language grants the power of attorney over the physical person of the principal. It should be accompanied by a court order finding that the statutory requirements for the supervised power of attorney have been met. If someone has a legally sufficient supervised power of attorney, that person will be able to produce such a court order without any difficulty. If the power of attorney also meets the durable power of attorney requirements, discussed below, then it could be used for health care purposes.

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Durable Power of Attorney

A durable power of attorney is a power of attorney by which the principal designates another person to be his or her attorney-in-fact and usually will take effect when the principal is unable to make his or her own business or medical decisions. This is the type of power of attorney that the physician almost always will encounter in the health care setting. The instrument used to create this type of power of attorney should state that it is being executed under the provisions in the Uniform Durable Power of Attorney Act and should contain the words *This Power of Attorney shall not be affected by subsequent disability or incapacity of the Principal, or lapse of time* or *This Power of Attorney shall become effective upon the disability or incapacity of the Principal* or similar words showing the intent of the principal that the authority conferred will be exercisable even if the principal later becomes disabled or incompetent. Any power of attorney which indicates that it is a durable power of attorney must comply with all of the requirements of the Uniform Durable Power of Attorney Act, including the specific statement that the power of attorney is intended to remain effective even after the principal becomes incompetent.

Prior to the amendments of the Uniform Durable Power of Attorney Act, a 1991 Attorney General opinion stated that a power of attorney could not be used to authorize health care decisions. After September 1, 1992, a durable power of attorney may be the instrument used to confer authority on another person to make health care decisions for the principal. The power may grant complete or limited authority with respect to the principal's person including, but not limited to, health and medical care decisions on the principal's behalf, but *excluding* the execution on behalf of the principal of a Directive to Physicians, a living will, an Advance Directive for Health Care, or any other document purporting to authorize life-sustaining treatment decisions. The durable power of attorney also may not be used to authorize the attorney-in-fact to make life-sustaining treatment decisions unless the durable power of attorney is combined in the same instrument with a health care proxy designation using language which complies with the requirements for a health care proxy under the Oklahoma Rights of the Terminally Ill or Persistently Unconscious Act. The power may also grant complete or limited authority with respect to the principal's real and/or personal property.

All acts performed by the attorney-in-fact pursuant to a durable power of attorney during any period of disability or incapacity of the principal have the same effect and bind the principal and his or her successors in interest as if the principal were competent to act for himself or herself. This means that if the person named as the attorney-in-fact in a properly executed durable power of attorney signs a consent form for treatment of the principal or authorizes the release of the principal's medical information, that authorization binds the principal and all other family members of the principal. This insulates the hospital and physician from liability other than for negligence or malpractice for acts taken based on the authority of an attorney-in-fact.

If, after the principal has signed a durable power of attorney, the court appoints a conservator or guardian of the principal, the attorney-in-fact must answer to the guardian in addition to the principal. The guardian has superior power over the attorney-in-fact and can revoke or amend the power of attorney executed by the principal. The principal may use the durable power of attorney to indicate the person he would want to be appointed as his or her guardian should he or she become incapacitated. The court then will follow the directions of the principal in appointing a guardian unless good cause is shown or the person selected to be guardian prior to the principal's incompetency is for some reason disqualified to act.

Death of the principal revokes and terminates the power of attorney. This means that if a patient has executed a durable power of attorney and then dies, the person named in the power of attorney no longer has any authority concerning the patient unless that person is also named as the personal representative of the deceased principal's estate. Thus, after such a patient's death, the hospital and physician should proceed as if there had been no power of attorney and follow its other applicable policies with regard to which family members may authorize an autopsy, release the body to a funeral home, and obtain copies of medical records.

A durable power of attorney does not need to be executed before a judge. However, the principal must sign the power of attorney before two witnesses who must also sign the document in the presence of the principal. All three signatures must be notarized. The witnesses must be at least eighteen (18) years of age and cannot be related to the principal by blood or marriage and cannot be the attorney-in-fact or anyone related to the attorney-in-fact by blood or marriage. The execution of the power of attorney must be in substantially the following form:

Signed:_____
(Principal's Signature)

City, County, and State of Residence

The principal is personally known to me and I believe the principal to be of sound mind. I am eighteen (18) years of age or older. I am not related to the principal by blood or marriage, or related to the attorney in-fact by blood or marriage. The principal has declared to me that this instrument is his/her power of attorney granting to the named attorney-in-fact the power and authority specified herein, and that he/she has willingly made and executed it as his/her free and voluntary act for the purposes herein expressed.

Witness:_____
Witness:_____

STATE OF OKLAHOMA)
) ss.
COUNTY OF TULSA)

Before me, the undersigned authority, on this _____ day of_____, 199____, personally appeared _____ (principal), _____ (witness), and _____ (witness), whose names are subscribed to the foregoing instrument in their respective capacities, and all of said persons being by me duly sworn, the principal declared to me and to the said witnesses in my presence that the instrument is his/her power of attorney, and that the principal has willingly and voluntarily made and executed it as the free act and deed of the principal for the purposes therein expressed; and the witnesses declared to me that they were each eighteen (18) years of age or over, and that neither of them is related to the principal by blood or marriage, or related to the attorney-in-fact by blood or marriage.

Notary Public

[SEAL]
My Commission Expires:

By executing a durable power of attorney using this form, a presumption is created that the principal understands the nature and purpose of the power of attorney and has executed the instrument voluntarily while being of sound mind. This allows the person dealing with the attorney-in-fact, such as the hospital or physician, to act without inquiring into the validity or adequacy of the execution of the power of attorney. For this reason, reliance on this type of power of attorney is relatively safe for the health care provider. If all the requirements described herein are met, then it is presumed that the power of attorney is valid and no one can question the physician's or hospital's reliance on it as a valid instrument. The hospital and physician may also presume that the witnesses meet the requirements of the law unless they have direct evidence to the contrary or reason to know otherwise.

Any durable power of attorney signed and dated *after* September 1, 1992, must meet the above described requirements in order to be valid. Thus, the hospital should not accept durable powers of attorney which do not meet these requirements if they are signed after that date. All powers of attorney executed *before* September 1, 1992, which met the requirements of prior law remain valid and, because of the amendments to the law, may be used to make health care decisions. To be valid under prior law, those powers of attorney must meet all of the requirements contained in the new law, except they do not have to be signed by any witnesses other than a notary and do not require the language set forth in smaller type above.

Finally, a power of attorney executed in another state may be considered valid under Oklahoma law if it substantially complies with the requirements of the Uniform Durable Power of Attorney Act set forth above. This means that if a durable power of attorney would be accepted for use by your hospital if it were signed in Oklahoma, it should also be accepted for use if it is signed in any other state. If it is not acceptable under Oklahoma law, it should not be accepted by the hospital no matter where it was executed.

Common Law Power of Attorney

Oklahoma case law recognizes powers of attorney in addition to those prescribed by statute. Common law powers of attorney are generally used in the context of property matters. Because common law powers of attorney terminate upon the incapacity of the principal, it is very unlikely that someone would try to use such a power of attorney in the health care setting. Logically, there is no reason to rely on a power of attorney which is not a durable power of attorney because if a person is capable of making his or her own decisions, that is the only person who may legally authorize or decline medical treatment. Therefore, it is unlikely that anyone will present a common law power of attorney to the health provider's staff.

Conclusion

Although there are three types of powers of attorney available under Oklahoma law, in most circumstances the only type of power of attorney which should be used in the hospital setting is the durable power of attorney which meets the requirements of the Uniform Durable Power of Attorney Act. The requirements of that Act are set forth above and must be met before the hospital should permit a principal named in a power of attorney to sign a consent form or a release of information form on behalf of the patient or former patient. Any time a durable power of attorney is relied on by the hospital, a copy of it should be placed in the patient's medical record.

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Health Care Tips for Your Professional Corporation II

or

Where There Is a Buy-Sell Agreement and an Employment Agreement, There Is a Way

Robert W. Gaddis

In my earlier article,[1] I discussed the importance of the Buy-Sell Agreement and the Employment Contract in the professional corporation (PC) environment. In that article the discussion was centered primarily upon the Buy-Sell Agreement and its structure. In this article, my comments will focus upon the shareholder Employment Contract with suggested provisions for language to enhance its efficacy.

AS YOU WILL RECALL FROM MY PREVIOUS ARTICLE, I indicated my predilection for suggesting little or no "good will" for small to medium size PCs. Under this view, the buy-out of the shareholder/employee's shares is generally based upon PC's "net book value," exclusive of receivables.

Typically, I handle shareholder receivables, in the buy-out scenario, as "termination compensation" in the Employment Contract. Earlier, when a favorable capital gains tax rate was available, there was a putative advantage to having a higher value for the stock and a lower value for termination compensation, since capital gains was available for tax treatment of the shares. Generally, however, this advantage was minimized because to accumulate "earned surplus," from which shares could be repurchased, the PC had to "retain earnings" which were then subjected to tax at the corporate rate.

In any event, with today's tax laws, it seems appropriate that receivables be handled as "termination compensation," since both capital gains and ordinary income are now taxed at the same rate. Additionally, the tax consequences to the PC are more straightforward since termination compensation is deductible by the PC, when paid, thereby preventing the PC from having to accumulate "earned surplus" with which to repurchase shares.

As mentioned in my earlier article, the importance of these documents cannot be underestimated. Our client files contain testimonials to the undisputed efficacy of such instruments. Plus, with health care reform on the horizon and concomitant "coalescing" of practices, PC structuring will be more important than ever.

In most instances, our firm represents the PC (rather than one of the shareholders, e.g.), and therefore, most of our documents are drawn for the overall benefit and continuity of the PC itself. This approach is generally consistent with the shareholders' wishes, since they prefer having strong documents favoring the PC and its continuity of life. Thus, when extenuating circumstances arise that might work a hardship upon a particular professional, the remaining shareholder(s), if there are ameliorating circumstances, may negotiate a more sanguine treatment than accorded from a plain reading of the agreements. Indeed, I have seen this approach used several times in my practice.

Conversely, when the behavior of a particular shareholder becomes obdurate and unmanageable, documentation favoring the PC is invaluable. Strong

[1] Gaddis, Robert W. Health Care Tips for Your Professional Corporation or Where There Is a Buy-Sell Agreement, There Is a Way. *J Okla State Med Assn* 1993, 86, 500-505.

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contracts provide the officers and directors with a means of quickly confronting a problematical professional and either rectifying the difficulty or obtaining removal from the group.

With today's unrelenting pressures on the practice of medicine, I believe it is imperative the PC have a high degree of control over its physicians. As discussed in my earlier article, in addition to typical (and increasing) liabilities arising from medical malpractice, there are incipient areas of liability for physicians and PCs relating to a physician's non-medical conduct, which may not be covered by insurance. Thus, it is important the PC have reasonable control over ensuring high medical standards and acceptable physician behavior.

Now, let's examine the Employment Contract and analyze certain provisions that will assist the PC in carefully defining its shareholder employer/employee relationship.

The Employment Contract

A. General. I have attached as Attachment A a specimen Table of Contents for a typical PC shareholder's Employment Contract. The Table of Contents provides an overview of the outline for these agreements. My discussions will focus on certain of these provisions and provide an analysis of their significance to the PC.

B. Employee's Duties and Services. This language is important, and is used to define a substantial portion of an employee's responsibilities to the PC and standards for the practice of medicine. The following language is illustrative of the provision I use for this section:

> General. Employee hereby agrees that during the full term of this Contract and any renewals or extensions hereof Employee will devote Employee's full time and attention to the practice of [specialty], exclusively for and on behalf of Corporation. Employee will faithfully and to the best of Employee's skill and ability diligently perform such duties and services as may, from time to time, be assigned to Employee and as required of a [specialty] including but not limited to the rendering by Employee of [specialty], diagnosis, consultation, and advice. Corporation shall have final authority over acceptance or rejection of any patient and assignment of patients to Employee. Corporation reserves the right to establish reasonable rules and regulations respecting the conduct and performance of duties of its employees, including Employee, and to establish work schedules for all its employees, including Employee. Employee agrees to diligently observe all such rules, regulations, and schedules, to carry out orders, directions, and policies of Corporation, whether communicated to Employee orally or in writing. Employee agrees during the full term of this Contract and any renewals or extensions hereof to conduct himself in such a manner as not to bring himself or Corporation into public or professional disrepute or in any manner that would subject Employee or Corporation to public ridicule or scorn or which would offend standards of public decency or morality. Nothing in this section shall be construed to require Employee to follow any directive or perform any act which would violate the ethics of the medical profession or any laws and ordinances regulating the practice of medicine.
>
> Practice Considerations. Employee shall observe and abide by:
>
> A. All ethical and professional considerations for the practice of medicine and surgery; and
>
> B. All federal, state and local laws, rules and regulations regulating the practice of medicine and surgery, including without limitation, regulations governing Medicare and Medicaid programs. Specifically, but without limitation, Employee shall not offer or accept any inducement for a Medicare or Medicaid referral or purchase of equipment or supplies, and shall describe accurately and truthfully, without miscertification, all services for which Corporation expects to receive reimbursement from any source.

This language is fairly self-explanatory. However, I call your attention to the last sentence of Clause B in the paragraph "Practice Considerations." This is a provision I have recently included in PC Employment Contracts to cover Medicare/Medicaid fraud and abuse concerns. Although these issues typically apply more to a hospital/physician transaction, fraud and abuse issues can also arise in the PC environment. Thus, it is important that physicians be aware of these rules and regulations, and that physicians comply with same so as not to create contingent liabilities for themselves, their other shareholders, and/or the PC.

C. Covenant Not to Compete. Although such restrictive covenants are enforceable if properly drawn, I have a slight aversion to their use based on solely philosophical reasons. When a shareholder desires to leave the PC, it is best for all parties, in my opinion, if an efficacious and expedient withdrawal can be arranged. In such circumstances, it places a burden on the withdrawing physician if the physician is unable to continue the practice of medicine within his or her extant service area. If parties become unhappy working together, this attitude may become apparent to patients and can compromise patient care, creating a dangerous environment. Accordingly, I believe, in general, it is better if a physician is not substantially restricted when departing the PC.

Nonetheless, we are all familiar with arguments for the contrary position. After explaining the options to my clients, they ultimately make the business decisions and I prepare language accordingly. Such covenants are, however, appropriate *during* the term of the Employment Contract to be certain the physician's services are solely for the PC's benefit, unless otherwise agreed.

D. Compensation of Employee. This language, of course, is the heart of the contract. However, the anatomy of this provision is highly variegated and multi-

faceted from one PC to another. Therefore, I routinely use a "compensation formula" approach for this covenant. With such treatment, compensation is a function of the physician's production (which I prefer to measure in "collections"), less overhead "allocated" to the employee.

Overhead allocation can become a delicate issue, especially with a wide difference between the high and low grossing physician shareholders within a group. Such a variation, however, seems more the norm than the exception.

I generally suggest a portion of the overhead (25% to 40%) be shared equally (the "fixed overhead"), and the balance (the "variable overhead") be shared in accordance with ratios established based upon each physician's collections as compared to the total collections for the PC's shareholder physicians.

This arrangement produces a certain amount of "fixed overhead," thereby providing an incentive for physicians to maintain their productivity. Concomitantly, this structure shifts a greater portion of the "variable overhead" to the higher producing shareholders, thereby not penalizing lower producing shareholders who may have a slightly different work ethnic or life-style than their higher producing counterparts. Work ethnic notwithstanding, there simply may be a wide income disparity between shareholders within a group based upon practice differences and procedures performed by the various professionals.

Obviously, the "compensation formula" approach requires that reliable and expedient accounting procedures are in place for the formula to work properly. Moreover, monthly computer-generated spreadsheets are essential for application of this modality. These calculations, however, are easy to achieve given the ready availability of competent accounting professionals and the widespread use of monthly, computer-generated practice management financial reports.

Indeed, when I am asked to assist a PC in reviewing and assisting with compensation practices, usually, the personnel and systems are in place with which to accommodate any changes we may wish to implement.

I am including below specimen language for employee compensation. However, I have omitted the compensation formula language, since this provision varies so greatly from one PC to another.

> Compensation Formula. Corporation agrees to pay and Employee agrees to accept as full and complete compensation for all services rendered by Employee under and pursuant to this Contract, the following amount resulting from the:
>
> [Insert compensation formula]
>
> Bonus. Nothing herein contained shall be construed to prevent Corporation from paying to Employee a bonus or bonuses during the term hereof or any renewals or extensions hereof if in the sole judgment of Corporation's Board of Directors a bonus is warranted to Employee.
>
> Expenses. Further, nothing herein contained shall be construed to prevent Corporation from reimbursing Employee for any reasonable expenses incurred by Employee for and on behalf of Corporation upon presentation of evidence and proper documentation thereof by Employee.
>
> Disallowance of Deductions. If a deduction shall be disallowed for either federal or state income tax purposes for all or any part of the compensation (or other benefits provided Employee) hereunder and Corporation shall be required to pay a deficiency (or elects to post a "cash bond," pursuant to applicable rules and regulations, pending resolution of the controversy giving rise to the deficiency) on account of said disallowance, Employee shall reimburse to Corporation an amount ("Deficiency Amount") equal to said deficiency (or the amount of the "cash bond," as the case may be), together with any interest and/or penalties applicable thereto. The Deficiency Amount must be paid by Employee to Corporation within ten (10) days after the date on which Corporation paid the deficiency (or the "cash bond") with respect thereto. Provided, however, in lieu of payment by Employee to Corporation, Corporation may, in its discretion, withhold amounts from Employee's future compensation payments, or other sums owed Employee by Corporation, until the Deficiency Amount has been fully recovered. Corporation shall not be required to legally defend any proposed disallowance by the Internal Revenue Service or the Oklahoma Tax Commission. The provisions of this paragraph shall survive the termination of this Contract, whether at the end of the term or prior thereto, and shall remain binding on Employee.
>
> Income Taxes. All compensation paid to Employee under this Contract shall be subject to the customary withholding taxes and other employment taxes as required by state and federal law with respect to compensation paid by a corporation to one of its employees. If this Contract is terminated for any reason other than normal expiration of its primary or any renewal or extended term, or for any other reason under the terms of this Contract, all monthly or annual compensation payable to Employee hereunder will be prorated, adjusted, and paid only to the date of such termination.

The "disallowance of deductions" language is slightly unique and gives the PC the ability to recover from the shareholder any expenses the PC incurs as a result of a disallowance of a deduction attributable to the acts of a particular shareholder.

E. Disability. Disability is also an area whose treatment varies widely from one PC to another. Some PCs may wish to provide a strong disability provision which might cover a physician for a period of up to one year, while other PCs choose a much shorter term. With specialty groups performing intricate, complicated procedures, I favor a shorter disability period (perhaps as short as ninety days). My physician clients are increasingly convincing me that individuals who are *fully disabled* for a period exceeding ninety days may have serious medical problems, which should be thoroughly reviewed before allowing the shareholder to resume practicing medicine.

Nonetheless, the structuring of disability provisions is a sensitive topic, and its treatment varies widely from one group to another. However, regardless of the PC's approach to disability, I always suggest the PC obtain adequate disability insurance on its physicians to provide resources with which to meet this contingency. Moreover, such insurance reduces the tendency for an impaired physician to continue practicing or resume practicing too soon.

Since disability provisions differ from one PC to another, I will not include specimen language for this provision. However, we typically find the following "fitness to return to practice" language useful:

> Fitness to Return to the Practice of Medicine and Surgery. Due to the complexity and intricacy of Employee's duties hereunder and to ensure optimal patient care, at the conclusion of any period of Employee's disability hereunder, a majority of Corporation's Board of Directors (excluding the disabled Employee if Employee is a director) must agree that the disabled Employee is fit to resume Employee's responsibilities as a [specialty] under this Contract, taking into consideration any applicable provisions of the Americans With Disabilities Act of 1990, as amended, balanced against the health and safety of Employee and Corporation's patients. Until such approval is given in writing, the disabled Employee may not return to work, but shall continue to receive Disability Compensation, subject to the provisions of this contract. Corporation shall consider, within fourteen (14) calendar days from the date of such request, Employee 's request for approval to return to work.

F. Termination. Termination provisions are extremely important in the PC Employment Contract to ensure that high medical practice standards are maintained at all times, and to give the PC authority to rectify improper physician conduct. The following is illustrative of our termination language:

> Events of Termination. This Contract shall terminate upon occurrence of the first of the following events:
>
> A. Whenever Employee shall cease to be a licensed physician and/or surgeon under the laws of the State of Oklahoma or any other state in which the Corporation is authorized to engage in business or the practice of medicine or whenever Employee is otherwise disqualified to or suspended from the practice of medicine and surgery under the laws of the State of Oklahoma or the laws of any other state in which the Corporation is authorized to engage in business or the practice of medicine.
>
> B. Whenever Employee loses staff privileges at any hospital regularly used by the Corporation's physician employees.
>
> C. Upon the death of Employee.
>
> D. Upon ninety (90) days' prior written notice by Corporation to Employee or by Employee to Corporation, subject, however, at all times to Employeee's notice of termination obligation herein set forth.
>
> E. Upon thirty (30) days' written notice to Employee, Corporation may terminate this Contract for "cause." If Corporation requests, Employee will continue to perform Employee's duties and be paid Employee's regular salary up to the date of termination. "Cause" shall mean neglect, willful misconduct, or malfeasance by Employee in the performance of Employee's duties hereunder, the breach of the terms of this Contract, the breach of any fiduciary duty owed Corporation, dishonesty, chronic absenteeism, chronic alcoholism or addiction to drugs which remains untreated and interferes with Employee's performance of duties hereunder, the conviction of a felony, or the conviction of a misdemeanor involving moral turpitude. Although otherwise qualified, Employee may deemed unqualified if Employee's conduct demonstrates an inability to work with other people at Corporation, if in the sole discretion of Corporation, such conduct may jeopardize patient care, Corporation shall have the right to terminate this Agreement subject to providing thirty (30) days' written notice to Employee.
>
> F. Failure to return to the employ of Corporation within ninety (90) days after the termination of military service.
>
> G. If Employee, because of mental, physical, or other disability, with reasonable accommodation, shall become unable to fulfill the substantial responsibilities of a practicing [specialty] and physician on a full-time basis for a period exceeding [disability period] after the date of initial disability.
>
> H. If Employee shall cease to own Employee's shares of stock in Corporation, either because of voluntary or involuntary transfer, sale or other disposition.
>
> I. Upon expulsion from the Corporation by two thirds (2/3) vote of Corporation's Board of Directors (excluding the Employee if Employee is a director), to ensure that patient care is not jeopardized taking into consideration the complexity and gravity of Employee's responsibilities hereunder as a [specialty].
>
> J. default by Employee of any of the terms, covenants, and obligations of this Contract which default remains uncorrected for a period of ten (10) days after written notice thereof by Corporation to Employee.
>
> K. Employee's retirement.

G. Termination Pay. As mentioned above, this is a key provision and is intended to compensate the withdrawing shareholder/employee (or estate) for receivables attributable to the physician's production existing on the PC's books and records at the time of the shareholder's separation from the PC.

There are a number of methods for determining termination compensation. However, in the medium to small PC (ten or fewer shareholders) I typically suggest that termination compensation be derived as a percentage of the PC's receivables attributable to the terminating physician's production. This percentage is ordinarily ascertained by first adjusting the "production" attributable to a terminating physician by the PC's usual collection ratio. For example, if the PC usually collects 75% of its receivables, the "production" attributable to a withdrawing physician/employee would be reduced by 25%. In most instances, many physicians and PC administrators would assume the resulting sum is the amount which should be distributed to the withdrawing shareholder as termination compensation. *However, such thinking fails to include* ***the cost of collecting these receivables*** *once the departing shareholder has withdrawn.*

Accordingly, an *additional reduction* to the with-

drawing shareholder's production should be applied to the "net collection" figure previously determined. This "cost of collection" reduction will vary from one PC to another, but, nonetheless, is a very real continuing cost of doing business. Thus, the "cost of collection" concept should be carefully reviewed by each PC and its shareholders.

The truth is, when a shareholder withdraws, the PC is *unable* to quickly reduce overhead attributable to the withdrawing shareholder—rent and equipment lease payments, for example, may continue for some period extending beyond the withdrawing shareholder's termination date. Moreover, collection of receivables will require maintaining sufficient staff to collect and process these accounts.

Additionally, one further point for consideration in calculating the amount of termination pay would be the extent to which the withdrawing shareholder complied with any "notice of termination" provisions required under the Employment Contract. Generally, if the employee fails to provide the requisite notice for the employee's voluntary withdrawal, some economic charge should be ascribed to the employee.

In the past few years, some of my PC clients have requested that "one-year notice of termination" requirements be used in Employment Contracts. At first I viewed this period as unreasonably lengthy, since I thought it might place an undue burden on a withdrawing shareholder who, for whatever reason, had decided to leave the PC. This reasoning was similar to my thoughts opposing the use of "non-compete clauses" as discussed above.

However, since my representation is generally focused at the corporate level, and realizing the difficulty and lead-time required in obtaining well qualified and *compatible* replacement physicians, the one-year notice requirement is seeming more reasonable.

Termination pay is generally payable over a six- to twelve-month period, usually commencing ninety days after occurrence of the "event" terminating the contract. This scenario is appropriate since it matches the receipt of revenues by the PC to the PC's termination compensation payment obligation.

In some instances (e.g., retirement), the parties may wish to provide for a longer payout, perhaps as much as twenty-four months. Generally, since this obligation represents additional compensation to the employee, termination pay, though paid in installments, will be non-interest-bearing.

One final point for consideration concerning termination pay is putting a "cap" on the PC's obligation for termination pay. This provision is somewhat parallel to the provision referred to in my earlier article concerning the option to dissolve the PC when two or more shareholders tender their stock for repurchase at the same time. The "cap" on termination pay provision is designed to protect the PC in the event two or more shareholders should terminate their employment at the same time and the PC wishes to continue its existence.

This is another of what I refer to as "safety valve" provisions designed to protect the PC and gives the PC greater flexibility in meeting (and surviving) unforeseen contingencies. The concept of this provision is simply to limit the amount payable monthly by a PC for termination pay, and to extend any such payment obligations over a greater period of time, subject to the PC's maximum monthly payments.

The following specimen provisions are illustrative of these intricate provisions:

> Termination Pay. Upon termination of this Contract, by either Employee or Corporation, Employee will be paid an amount ("Termination Pay") in accordance with the following provisions:
>
> A. Death, Disability, or Retirement. If termination of this Contract occurs as the result of Employee's retirement (as described in Paragraph _ above and subject to the (12) twelve month notice provision therein and herein contained), death, or disability, Corporation shall provide Termination Pay to Employee, Employee's estate, or Employee's legal representatives, as the case may be, in consideration of Employee's past service on behalf of Corporation. Such Termination Pay shall be an amount equal to ["net collection percentage"] (%) of Corporation's accounts receivable attributable to medical services performed by Employee while employed hereunder, as further reduced by [cost of collection percentage] percent (__%) to cover Corporation's cost of collection of same, as further reduced by all accounts payable due Corporation from Employee. Said Termination Pay shall be payable in ___ equal, consecutive, monthly installments with the first such installment commencing ninety (90) days after the occurrence of the event terminating this Contract.
>
> B. Other Events of Termination. In the event of termination hereof due to any other reason than as specified in the immediately preceding Paragraph A, Termination Pay shall be calculated as determined in said Paragraph A, except the sum determined to be due Employee shall be paid in ___ equal, consecutive installments.
>
> C. Employee Voluntary Termination Notice Requirement. Notwithstanding anything herein to the contrary, except in respect to death, disability, or retirement at age [insert agreed-upon normal retirement age], in the event of Employee's voluntary termination of this Contract, Employee shall provide Corporation with not less than twelve (12) full calendar months prior written notice of such termination so Corporation may arrange for a well-trained replacement [specialty] physician and to provide for optimal continuing care of its patients, especially realizing the difficulty and time required to obtain the services of a well qualified replacement [specialty] physician. In the event Employee fails to provide such twelve (12) months prior written notice to Corporation, any sums due Employee from Corporation, pursuant to this Contract or otherwise, shall be reduced by:

[Insert formula language for "insufficient notice" charge]

H. Release. I typically include some form of "release language" in the Employment Contract in an attempt to extinguish the PC's liability to a withdrawing shareholder upon payment of any sums due such physician. The following language is illustrative of this concept:

> Release. Payment of Termination Pay hereunder shall constitute satisfaction of all obligations of Corporation to pay Employee compensation of any kind, and Employee shall not be entitled after termination to any further interest in accounts receivable or any bonuses or other payments. Acceptance of such Termination Pay by Employee or his legal representative shall release Corporation from any and all claims from Employee or his legal representative, whether vested or contingent, of any nature whatsoever, arising out of, or in any manner associated with, the terms of this Contract and/or Employee's employment by Corporation.

I. Hold Harmless and Indemnity. This is a significant provision, and you will notice the language I have provided below is broad and attempts to cover all claims arising from any employment-related concerns, including Medicare/Medicaid. In addition to malpractice, other claims covered under a comprehensive indemnity, could include, for example, sexual harassment. If such charges are the result of the withdrawing shareholder's actions, the shareholder should indemnify the PC.

Moreover, with the complicated rules pertaining to Medicare/Medicaid reimbursement programs, it is also appropriate to specifically require the withdrawing shareholder/employee to indemnify the PC from claims which might occur in this regard, including, for example, miscertification and/or improper coding. Emphasis on such indemnities will probably become more pronounced as greater regulatory controls are imposed on the practice of medicine. The following language is an illustrative indemnity provision:

> Hold Harmless and Indemnity. Notwithstanding anything herein to the contrary, Employee expressly agrees to hold Corporation, its directors, officers, employees, and agents, harmless from, and indemnify and defend against any and all claims of whatsoever nature arising out of or in connection with Employee's engagement hereunder, including, but not limited to claims arising from Medicare/Medicaid or malpractice. This provision shall survive the termination of this Contract, whether at the end of the term hereof or prior thereto, and shall remain binding on Employee.

J. Miscellaneous Terms and Conditions. Most of these provisions are typically routine boiler plate. However, as referred to in my earlier article, there are two particular points I believe should be included which would be particularly helpful in the PC environment. First is the provision binding the parties to the financial calculations made by the PC's regular accountant. Second is the language awarding attorneys' fees to a prevailing party in the event of a dispute. Examples of language for these provisions are contained in my previous article.

The "attorneys' fee" covenant is a "double-edged sword." However, this language will keep the parties at the negotiating table, in the event of a dispute, rather than precipitously pursuing costly litigation, which, in my experience, has generally been substantially more beneficial to attorneys than physicians.

Conclusion

As may be seen from the foregoing discussions, a seemingly innocuous Employment Contract is a complex document embodying many intricate and subtle nuances. Nonetheless, if the Employment Contract and the shareholder's Buy-Sell Agreement are carefully reasoned and artfully drawn, the PC should be able to maintain long-term continuity of life, while meeting unforeseen contingencies, and providing a vehicle for the admission and withdrawal of its shareholder physicians—or, as the medical maxim states: *Non vis sed arte—"Not force but art..."*

The Author

Mr. Gaddis is vice-president and a director of the Tulsa law firm of Barrow Gaddis Griffith & Grimm, Inc.

ATTACHMENT A

[NAME OF PROFESSIONAL CORPORATION]
[PHYSICIAN'S NAME], M.D.
[DATE]

SPECIMEN

EMPLOYMENT CONTRACT

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EXHIBITS:

Exhibit A —Letter of Good Standing from the Oklahoma Board of Medical Licensure and Supervision.

Exhibit B —Board of Directors Minutes authorizing PC to enter into Employment Contract.

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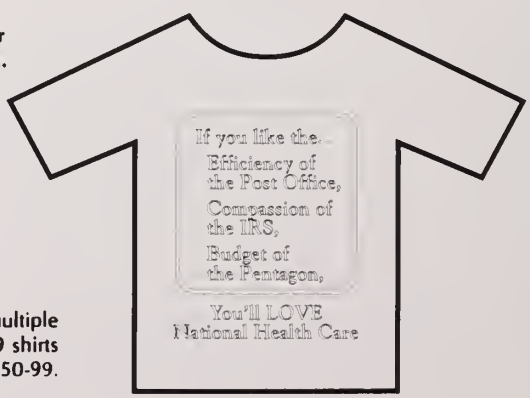
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Health Access Oklahoma

OSMA tackles health care reform with its own game plan

Since late September, OSMA officers and trustees have been on the move, criss-crossing the state to present the association's alternative to the health care reform plans of state and national politicians.

In the series of fifteen meetings, OSMA leaders explained how the association, by offering its own plan, Health Access Oklahoma, can incorporate a managed care segment designed by and for practicing physicians. The meetings gave state physicians an opportunity to participate actively in the planning process by listening, questioning, suggesting, and criticizing.

According to Dr. Douglas C. Hubner, chairman of the OSMA Board of Trustees, "Unless physicians are willing to provide the leadership, direction, and risk for such a venture, other non-physician entities will undoubtedly exploit this health care opportunity into somebody else's creation" (*Tulsa Medicine,* October 1993).

For those who were unable to attend one of the meetings, the following is the text of the presentation. The OSMA invites and encourages your comments on Health Access Oklahoma.

HEALTH ACCESS OKLAHOMA—A HEALTH SYSTEM REFORM PROPOSAL DESIGNED BY PHYSICIANS FOR PATIENTS

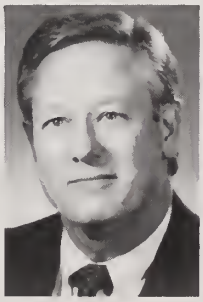
For over thirty years—since the beginning of the debate on Medicare in the early sixties and before—physicians have warned the American people that our health care delivery system was headed for chaos.

While it was an admirable goal thirty years ago to want to provide health care for our senior citizens, physicians went unheeded—indeed, we were even castigated—when we cautioned that the design of the Medicare system was flawed and inadequately funded. The American Medical Association correctly predicted that Medicare costs would quickly spiral. No one listened.

When physicians sought relief from the mountains of paperwork generated by the bureaucratic scrutiny of government and private insurers—and when we explained and documented how this new medical bureaucracy added to the cost of medicine, no one cared.

When physicians called for tort reform and clearly demonstrated that the cost of defensive medicine added billions to the cost of health care in this country, we were called self-serving.

In the mid-eighties, the AMA spent several million dollars and assembled medical leaders, scholars, scientists, captains of industry, and representatives of labor and asked them to develop a health care agenda for the American people. That document, which took two years to produce and contains many of the recommendations we hear coming out of Washington today, was presented to Congress, the media, and the American people. They ignored it.



Dr. Lance Miller
President

The AMA's Health Access America proposal was introduced three years ago. It pre-dates just about any other health system reform proposal. Health Access America is only now receiving the recognition it deserves.

While physicians have advocated health system reform for over thirty years, it wasn't until the cost of health care became an issue in last year's presidential campaign that the public and the politicians became interested in the issue.

Now everyone seems to have a plan to reform the health care delivery system. We can argue about how much change actually is needed, but the political reality of the situation is that the way we as physicians deliver and the way we as a country pay for health care is about to change. We are about to enter a new medical environment, indeed, a new era in medicine.

The problem that we physicians have as this new day approaches is that it is the politicians, the bureaucrats, and the insurers who want to design and manage the change without consulting practicing physicians and thereby control us and our patients.

This simply is unacceptable. While physicians must protect our interests, it is more important to guard and protect the welfare of our patients.

Who puts patients first? The government, which is really interested in cost containment? Bureaucrats, who

are dedicated to perpetuating their employment? Insurance companies, which are interested in the bottom line? None of the above.

Who puts patients first? The answer, of course, is physicians. But in these changing times, physicians must act boldly, must take risks, if we are to remain advocates for our patients, if we are to preserve the doctor/patient relationship, and if we are to ensure the right of our patients to select the physician of their choice.

To achieve these ends, the Oklahoma State Medical Association is about to undertake two of the most ambitious and important projects in its history. That's why we are here—to share with you how the OSMA is positioning itself to be a major player in the arena of managed care and managed competition. We also want and need your input and suggestions as our association plans for the future of its members and their patients.

The OSMA wants Oklahoma physicians to be the managers in this new era of managed care. So we are here to talk about two things; first, the establishment of a statewide network of physicians, an entity designed and run by physicians with their patients in mind that will compete in the new Oklahoma medical marketplace.

The OSMA wants to help define the new medical market, so the second thing we will discuss is Health Access Oklahoma, a standard benefits package with specific funding recommendations that will be presented to the Oklahoma Legislature next February as a physician-designed alternative to other health system reform packages.

Statewide Physician Network

Let's turn first to the creation of a statewide physician network and describe alternatives our Board of Trustees considered before voting to commit the OSMA to this project. We will also take a look at potential risks and potential rewards and just what it will take to make it work.

While it lacks precise definition and may mean many different things to different people, it is clear that managed care is a major component in most health reform proposals. It certainly is favored by the White House and many legislators, including those in Oklahoma. Again, we can argue for hours whether managed care is the most effective method of reform, but the political reality is that managed care is an acceptable alternative to those who ultimately pay for health care—the government, insurers, and employers who purchase health benefits.

The Oklahoma Legislature has decreed that the state's Medicaid program will operate under a managed care system by 1995. It was due to this political reality that the OSMA first began to explore the idea of a statewide provider network. OSMA Immediate Past President Dr. Jim Funnell established an ad hoc committee on managed care. Tulsa's Dr. Burr Lewis personally inspected and reported to the committee on the workings of the Arizona health care cost containment system, a Medicaid managed care program that appears to be at least reasonably well accepted by Arizona physicians.

Our board, after deliberate and thoughtful debate, voted to proceed with the development of a statewide physician network.

But as the managed care concept drew more and more supporters, members of the ad hoc committee on managed care realized the real possibility that physicians could lose their autonomy under this system where medical decisions could be affected by actuaries and accountants more interested in the bottom line than quality of medical care.

Therefore in order to ensure that physicians retain control of the system, in order to ensure that patients—whether government or private pay—remain able to keep their own physician or select a new one of their choice, the ad hoc committee on managed care recommended that the OSMA form a statewide network of physicians.

The OSMA Board of Trustees had a decision to make. Did it accept the recommendation? If so, how would the plan be implemented?

Our board met to consider its options and quickly agreed that it had to do something. But what?

The first question it had to answer was: What is the basic goal to be achieved?

Since physicians are skeptical about managed care and its possible effects on their practice styles and the health of their patients, the board decided the OSMA must strive to produce a system that:

- Is physician and patient friendly
- Is efficient and cost effective without sacrificing quality of care
- Allows medical decision-making to be left to physicians
- Is controlled by physicians
- Provides physicians the leverage to compete in the new medical marketplace

Could this be achieved without forming a statewide physician network?

One alternative to forming a physician contracting network would be to create an organization that would supply services to managed care entities and third party payers. One of the principal functions of managed care organizations is to oversee utilization of services and quality of care received by beneficiaries.

Unfortunately some managed care plans have difficulty incorporating sound medical judgments into the oversight of utilization and quality. Who better to provide utilization review and quality assurance services than physicians? And medical societies are well equipped to provide these services. Our membership possesses the medical expertise necessary to assess the appropriateness of a wide range of medical treatments. Patients would very likely find it attractive to have clinical decisions reviewed by physicians rather than ancillary health professionals or "bean counters."

Other services a medical society could offer to a managed care company are risk management and grievance adjudication.

Would providing these services enhance the ability of the OSMA to promote the use of clinically valid screens and review criteria that are agreeable—or at least less disagreeable—to physicians? The answer is probably yes.

Would an OSMA-run utilization review and quality assurance organiza-

tion have a substantial impact on the way care is delivered in the state? It most certainly would.

But would providing these services offer physicians any more control or any greater leverage in the new medical marketplace? Our Board of Trustees thought the answer to that question was no.



Dr. Jay Gregory
President-Elect

Some medical societies have discussed expanding consulting and educational services as a way of preparing their members to deal with managed care. Others advocate intensified lobbying efforts to increase regulation of the managed care industry or becoming more involved legislatively in health care reform.

The OSMA already is active in all of these areas. And pursuing this strategy would not offer physicians the control and leverage we will need to ensure quality medical care for our patients.

It is interesting to note here that much of the discussion on whether or not there is a need to form a physician network broke down along rural and urban lines. Right now physicians outside the greater Tulsa and Oklahoma City metropolitan areas are much less used to dealing with—and much less threatened by—managed care entities. Trustees from rural Oklahoma talked of pleasant and productive working relationships with their hospitals and local employers. Patients in rural Oklahoma are loyal to their doctors and few are enrolled in HMOs, PPOs, or other managed plans.

Initially rural trustees said many of the physicians they represent probably would see little need to form any kind of organization.

Urban trustees, on the other hand, described a Machiavellian world of alliances between hospitals and hospitals, HMOs and hospitals, employers and HMOs, Oklahoma City hospitals and Tulsa hospitals, and on and on—all scrambling to control the system and to control physicians. Urban physicians pointed out that not only are hospitals in Oklahoma City and Tulsa attempting to change referral patterns through outreach programs, practice acquisitions, and satellite clinics, but hospitals in Oklahoma's other major cities are in the process of doing the same thing themselves.

And Trustee Dr. Noble Ballard finally reminded the board that it was only a few short years ago that state and education employees in Altus and all over the state of Oklahoma formed daily caravans to drive to Oklahoma City for care. This is one of the reasons we are here—to let you know that whether you practice in urban or rural Oklahoma, you are not immune to the effects of managed care.

So our board, after deliberate and thoughtful debate, voted to proceed with the development of a statewide physician network.

But what form should this network take?

There are essentially two options—create a physician contracting network like an IPA or PPO, or form a physician-run managed care organization.

However, for a medical association to form any kind of physician network there are questions to be asked and risks to be considered.

First, will all medical society members be invited to participate in the plan or will participation be limited? A limited panel that excluded members would cause widespread alienation for a substantial part of our membership. Therefore any plan established by the OSMA will be open to all who wish to participate.

This any-willing-provider policy leads directly to a second question: Is the medical association ready to adopt stringent utilization review and quality assurance mechanisms to oversee the care provided by participating physicians?

A full-service, physician-run managed care organization will give us the control we need to ensure our patients will continue to receive high quality care.

The answer, as it has to be, is yes. Our members must know up front that the establishment of a physician network by the OSMA does not mean the continuation of "business as usual." Any network formed by the OSMA will be required to collect data regarding utilization and to compare physician practice patterns to established norms. In some situations it may be necessary to take action against physicians whose practice patterns indicate excessive utilization or inadequate quality. Our board feels that since our organization will be physician-run, any utilization or quality actions will be accomplished in the spirit of education. Nevertheless, there may be situations when, after appropriate counseling, a physician who continues to be an outlier will no longer be able to participate in the program.

Since failure is the biggest risk faced by a physician network, the next question to ask is: Is there a market for the network? Our Board of Trustees thinks the answer is yes. One major selling point to employers and other purchasers of health care benefits is the statewide access the network would provide. This feature could become even more attractive if President Clinton's vision of regional health care purchasing cooperatives becomes a reality.

And much has been learned from the failure of several medical society–sponsored IPAs in the early eighties. Since 1986, the Connecticut State Medical Society has operated an IPA-model HMO known as M.D. Health Plan. Today the plan has 75,000 enrollees and revenues of approximately $100 million per year.

In addition, the South Dakota State Medical Association has operated an IPA-model HMO known as Dakota Care since 1986. The plan has 30,000 enrollees, mostly from small businesses.

Like Oklahoma, several other state medical associations are in various stages of establishing physician networks.

Having just described two successful physician-run organizations, this is a good time to offer a word of assurance about anti-trust. While anti-trust is a concern and must be considered at every step along the way in the formation of a physician network, both AMA and OSMA legal counsels believe that anti-trust laws do not impede nor preclude the creation of a physician network. Neither Connecticut nor South Dakota have experienced anti-trust problems.

The easiest way for the OSMA to establish a physician network would to

organize an individual practice association. An IPA is not an insurance company so it does not require capitalization and does not have to meet any laws or regulations relating to insurance companies. An IPA contracts with self-insured employers and HMOs that perform the insurance function.

But would an IPA give physicians the control, the leverage that we will need to be the managers in the era of managed care? Our Board of Trustees thinks the ultimate answer is no.

While the formation of an IPA probably will be a necessary first step, if we stopped there the OSMA and Oklahoma physicians would just be another player in the game.

Right now it is the feeling of the board that if we are going to test the waters, we might as well dive in all the way and create a managed care organization combining the best aspects of IPAs, PPOs, and HMOs. Our proposed managed care organization will be a full-service health insurance company.

Forming an organization that bears insurance risk is far more complicated and risky than creating a network that simply provides medical services.

A medical society that forms a managed care organization must comply with state laws regulating the minimum capital reserves that an insurer must maintain and—even more importantly—that capital must be raised.

But despite the risk, would a physician-run, full-service managed care organization allow physicians to compete in the new medical marketplace? Again, our Board of Trustees thinks the answer is yes.



Dr. Joe Crosthwait
Co-Chair
HAO Task Force

A managed care organization that could provide services statewide should prove to be very attractive to large employers, state government, and even other HMOs, IPAs, PPOs, and health insurance companies. A physician-run managed care organization also would be able to tailor health insurance products for small businesses and the Medicaid program. A full-service, physician-run managed care organization will give us the control we need to ensure our patients will continue to receive high quality care. Physician-directed utilization review and quality assurance will ensure cost effectiveness and quality, and that combination should give us leverage with the purchasers of health care benefits, whether in the public or private sectors. The experiences in Connecticut and South Dakota demonstrate that it can be done.

And remember, the OSMA has a successful record in the insurance business; just look at PLICO. PLICO, our company, provides professional liability insurance for nearly 4,000 Oklahoma physicians and health and accident insurance for nearly 20,000 of us, our families, and our employees.

Questions remain and we seek your input either here or by letter when you return to your office. Should the managed care organization be run on a for-profit or not-for-profit basis? Should it be owned by the OSMA like PLICO? Should the OSMA manage it? If not, who should? Who should capitalize the managed care organization and for how much? Please let us know what you think.

Health Access Oklahoma

Now let's turn to Health Access Oklahoma. It has been clear for some time that the cornerstone of any health system reform effort will be a basic package of health care benefits that will be available to all Americans. It also is evident that any federal reform plan will allow states the leeway to design plans that will meet their particular needs. Those who wish to be managers in the new era of managed care will be asked to bid on the cost of providing the basic benefits to various patient groups.

The governor's commission on health care has designed a reform package with some excellent ideas but also some controversial ones.

To ensure that the Oklahoma Legislature has an alternative plan to consider, one designed by physicians with patients in mind, OSMA President Dr. Lance Miller appointed the Health Access Oklahoma Task Force. He asked Oklahoma City's Dr. Joe Crosthwait and Tulsa's Dr. Ted Brickner to serve as co-chairs.

The task force had several goals:

- To develop a set of medically necessary health services accessible to Oklahomans at an affordable price
- To make the plan portable from one employment to another to assure the continuation of the availability of these health services
- To guarantee renewability and insurability to all Oklahomans
- To provide a mechanism for the insurability of the underinsured and the previously uninsurable

Health Access Oklahoma recommends that all Oklahomans—except those covered by Medicare, CHAMPUS, the Indian Health Service, or recipients of veterans health benefits—be covered by a standard benefits plan. It is essential to cover all Oklahomans, including dependents, in order to eliminate cost shifting, the practice of physicians and hospitals charging insured patients more in order to subsidize low- or no-pay patients.

The Health Access Oklahoma Task Force has developed a standard benefits package. That package has been given to actuaries to determine just how much it will cost. When the actuaries return their report, it may well be necessary for the task force to meet again to fine tune the product.

The OSMA will share the final version of the standard benefits plan with specialty society presidents and other interested members. But I must emphasize here, and emphasize strongly, the OSMA standard benefits plan must be competitive with plans recommended by federal and state government and others.

I mentioned earlier in talking about the proposed managed care organization that the future would not be more "business as usual."

Our standard benefits package, developed by our task force that included representatives from diverse specialties, will contain a basket of medically necessary goods and services.

Will it contain every service that every specialty thinks is medically necessary?

The answer, quite frankly, is no. There is just no way that can happen. When the standard benefits plan is fi-

nalized, your constructive criticism will be sought and welcomed. Please remember, we are talking about a set of basic benefits. For our plan to receive serious consideration, it cannot be priced out of the market.

How will the standard benefits plan of Health Access Oklahoma be funded?

Employers or an employer/employee combination will be required to purchase at least the standard benefits package for all employees.

The self-employed and individuals will be required to purchase the standard benefits plan individually.

The cost of the standard benefits plan to employers, the self-employed, and individuals will be deductible from federal and state income tax.

Medicare recipients will be insured through the Medicare trust fund and supplemental Medicare policies. Public funds will assist those Medicare recipients who, after means testing, are determined to be unable to purchase supplemental policies.

Medicaid recipients will be covered by the Medicaid trust fund supplemented by public funds if necessary.

The uninsured and underinsured will be means tested. For those who cannot afford the standard benefits plan, public funds will be used to cover the cost of their coverage.

How will the state raise the funds necessary to provide the standard benefits plan to those who cannot afford it?

In addition to the use of the Medicare and Medicaid trust funds, Health Access Oklahoma recommends:

- A tax on tobacco, liquor, wine, and beer
- Increased income taxes or a value added tax
- Sales tax
- Insurance premium tax

It is essential that an ERISA exemption be obtained so that community rating can be attained and a premium tax can be collected on self-insured plans.

Health Access Oklahoma recommends the establishment of a health benefit card system. The benefit card will be purchased by the funding entity for the recipient, for example, the employer will purchase the card for the employee, Medicaid for the Medicaid recipient. The card would be presented whenever a patient received care. The health benefit card will be negotiable only for health care services.

To guard against over-utilization of the standard benefits package, a co-pay at the point of service is recommended. The amount of the co-pay will depend on means testing and will be calculated to discourage unnecessary utilization without affecting medically necessary care.

The creation of a statewide network will make us formidable competitors in the new medical marketplace.

Regulation of the standard benefits plan will be the responsibility of the state insurance commissioner. Means testing will be administered by the appropriate state agency.

The standard benefits plan will be implemented in an orderly fashion. Groups most in need of health insurance will be phased in first. The order of inclusion will be the uninsured followed by the underinsured, Medicaid recipients, and finally those who have health insurance.

Health Access Oklahoma also recommends the creation of a risk pool to cover those with diseases or conditions normally considered uninsurable and to protect against catastrophic losses. A monetary limit will be established to lessen the loss of the regular insurance policy. Once it is reached, additional expenses will be paid from the risk pool.

Any credible health reform proposal must address cost containment. Therefore the Health Access Oklahoma standard benefits plan will be subject to prospective, concurrent, and retrospective utilization review with case management where appropriate.

But cost containment means more than utilization review. It also means that something has to be done about the high cost of defensive medicine—and we all know that means tort reform.

Health Access Oklahoma recommends the following:

- Elimination of joint and several liability
- Mandatory offset of collateral sources
- Periodic payment of awards
- Limitation of non-economic awards to $150,000
- Limitation on the period for the suspension of statutes of limitation in cases of minors
- Immunity from civil negligence claims when following state approved and propagated practice parameters
- Judicial establishment of attorney contingency fees based on a sliding scale
- Legislation which would more precisely and narrowly define the grounds for the use of punitive damages in negligence suits

The OSMA feels that Health Access Oklahoma:

- Retains a free market approach to health care delivery
- Provides a reasonable basic benefit plan for for all Oklahomans including the disadvantaged in our state and establishes a standard benefit plan for everyone which can be enhanced by those who wish to purchase additional coverage
- Recommends a phase-in for different covered groups to avoid strain and confusion of a new system

The OSMA has shared Health Access Oklahoma with the leadership of the state legislature. While it is unclear whether any substantive health care system reform will occur in an election year, the leadership has welcomed Health Access Oklahoma as a positive, proactive, practical plan for health care reform. Health Access Oklahoma makes us players in the game.

Although we have a lot of work to do, we are well positioned to do it.

The creation of a statewide network will make us formidable competitors in the new medical marketplace. Health Access Oklahoma arms us with a plan and a product that will keep physicians and their patients as the managers of their health care.

We will keep you informed of our progress. We ask for your patience, your criticism, and your cooperation. Remember, we are all in this together. So let's continue to work together for ourselves and our patients.

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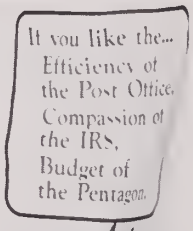
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T-shirts express skepticism as health care reform advances

The T-shirts that captured the fancy of OSMA members at last April's Annual Meeting are gaining in popularity as the details of President Clinton's health care reform become known.



"The T"

You remember the message—IF YOU LIKE THE... EFFICIENCY OF THE POST OFFICE, COMPASSION OF THE IRS, BUDGET OF THE PENTAGON, YOU'LL *LOVE* NATIONAL HEALTH CARE.

Now OSMA members can order the humorous, attention-getting apparel for themselves, their staff members, and their friends and families. The shirts are being sold by the Concerned Doctors of America, an organization founded by the shirt's originator, Bob McLauchlin.

McLauchlin, president of the Oklahoma City–based office management company that distributed the shirts at the Annual Meeting, has taken his concern one step further and founded Concerned Doctors of America (CDA). Membership is open to physicians and health care professionals who believe they should be "as visible and vocal as possible" in alerting the public to the widespread negative propaganda and misconceptions about the medical profession.

"My father is a retired physician and I know about the hours, the risks, and the sacrifices. It seems like doctors are being painted as the bad guys in the atmosphere of political propaganda that illustrates the American health system as substandard," says McLauchlin in the October 1993 *Bulletin* of the Oklahoma County Medical Society. "We simply need to utilize the mass media to convince the patient that his or her doctor is NOT the only good one out there! They need to know that the average doctor is like their own trusted physician."

OSMA trustees were so taken with the CDA's goals that they voted at their August 22 meeting to assist in the organization's public education campaign, which also includes commercials on local television. As part of that support, the JOURNAL is donating space to the CDA for promotion of its T-shirt sales. An order form appears on page 562.

While the ultimate effectiveness of the T-shirt campaign is difficult to assess, at least one satisfied owner reports that her shirt often draws smiles and comments from passers-by, and recently, even some specific questions about health care reform.

New program targets OKC's high white infant mortality rate

According to the latest statistics, Oklahoma City boasts the highest white infant mortality rate in the nation for cities its size.

A comparison of cities over 250,000 population released by City Match and based on information from the National Center for Health Statistics shows that Oklahoma City ranks worse than every other large U.S. city except Washington, D.C. And black infant mortality rates are higher than those of white infants, even though several other cities have rates which outrank Oklahoma City's.

Specifically, 12.14 white infants per 1,000 live births died under one year of age during the years 1985 through 1989. Black infants died at a rate of 17.84 per 1,000 live births during that time.

The year-old Oklahoma Fetal and Infant Mortality Analysis Program is actively working to solve the problem, through a concerted, organized effort of more than 75 local professionals with talents in three specific areas—clinical, epidemiological, and managerial. They are working under the guidance director Jane Hughes, RN, MPH, and Medical Director Roger E. Sheldon, MD, professor of pediatrics at the University of Oklahoma Health Sciences Center in Oklahoma City.

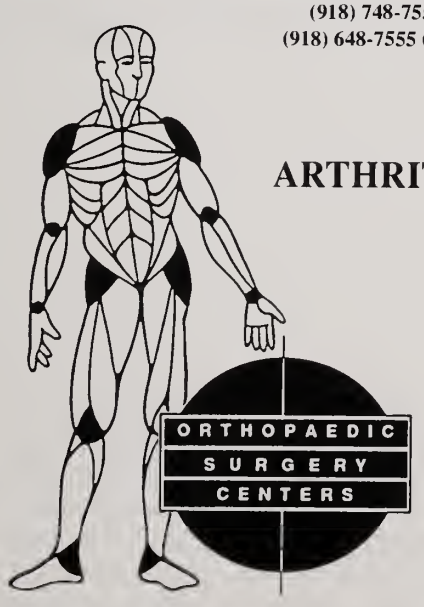
In their initial effort, program professionals are analyzing 1992 Oklahoma County fetal and infant death statistics, using hospital logs, medical records, and other sources. Names and other identifying information are being removed from the records and the remaining information analyzed. The information will then be stored in a computerized database and scanned for trends that are adversely affecting fetal and infant health.

Local professionals and leaders also are participating in two types of committees to identify contributing factors and develop strategies to reduce local fetal and infant mortality rates. Their job is to come up with final recommendations on how best to ensure that fewer babies die in Oklahoma. The answers, program participants say, will involve the entire community, not just the medical agencies.

The program brings together health care, social service, education, and religious community professionals whose talents are essential in studying and affect-

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Needed family planning services available at 102 sites statewide

Current data indicate that public family planning services are beneficial in terms of both public cost and individual health. Research shows that for every public dollar spent on contraceptive services, up to $6.50 is saved that would otherwise be needed for birth-related costs, Medicaid, AFDC, food stamps, and WIC.

The Oklahoma Family Planning Program is funded with federal, state, and local funds. The program provides citizens with the information and means to determine the number and spacing of their children. The program is targeted to serve indigent women as a priority but any man or woman seeking services can receive them. Individuals whose income is less than the federal poverty level pay nothing, and there is a sliding scale for all others. Services are provided in 102 clinic sites across the state utilizing both county health departments and private non-profit contractors.

Most people associate family planning with birth control since it has proven to be an effective tool for controlling reproduction. Research from the Alan Guttmacher Institute indicates for every 1,000 women using reversible contraceptives, 260 unintended pregnancies are prevented each year including 112 births and 114 abortions. Based on this information as well as current caseload, 15,080 unintended pregnancies were prevented during CY 1992. This includes 6,496 births, 6,612 abortions, and 1,972 miscarriages.

However, data from the Pregnancy Risk Assessment Monitoring System (PRAMS) indicates that 44% of all live births in Oklahoma still result from unintended pregnancies. Unintended pregnancy is defined as pregnancy among women who did not want to become pregnant at that time (mistimed), or did not want to ever have a baby (unwanted). Of women who had a live birth in Oklahoma between 1989 and 1991, one of every three reported their pregnancy was mistimed, while one in seven new mothers reported their pregnancy was unwanted. Surprisingly, 78% of the unintended births in Oklahoma were to women who were 20 years or older.

In CY 1992, the Family Planning Program served approximately 58,000 men and women. Ninety percent

Infant mortality *(continued)*

ing change in the area of women's and infants' health on a statewide basis, Ms. Hughes and Dr. Sheldon say. The three chief collaborating agencies include the OU College of Medicine—Department of Pediatrics, the OU College of Public Health, and the Oklahoma State Department of Health.

Preliminary findings have produced both expected and unexpected results, and mirror some surprising new information, including:

- College-educated women are drinking more during pregnancy.
- Increased access to prenatal care does not mean that women will take advantage of it.
- Cities boast higher infant mortality rates than rural areas.
- Language difficulties are one barrier to obtaining prenatal care and infant care.

Poor or non-existent prenatal care is not the only reason for infant deaths.

"There are multiple factors," Ms. Hughes says. "There also may be environmental and biological factors we are not yet aware of," says Dr. Sheldon. "Our job is to come up with final recommendations on how best to make sure fewer babies die in Oklahoma. But we feel already that these answers will involve the entire community, not just the medical agencies. The answer, at least partly, will lie with social services."

The Oklahoma Fetal & Infant Mortality Analysis Program has applied for funding from the National Fetal-Infant Mortality Review Program, sponsored by the American College of Obstetricians and Gynecologists, which should allow for acceleration of its efforts, Dr. Sheldon says.

In addition to Dr. Sheldon and Ms. Hughes, steering committee members for the program include Dr. J. Chris Carey, chief, Division of Gynecology, OU College of Medicine; Dr. Linda Cowan, associate professor of biostatistics and epidemiology, OU College of Public Health; Dr. Brian Lepley, pediatrician; Joy Leuthard, program director, Healthy Futures, Oklahoma State Department of Health; and Richard R. Lorenz, director, Planning and Evaluation Section, Oklahoma State Department of Health.

For more information about the program, call (405) 271-6625.

Family planning services *(continued)*

of these clients are women whose income was less that 150% of the federal poverty level. This represents services provided to 40% of the targeted women in need in Oklahoma. Based on research from the Guttmacher Institute, it is estimated that an additional 82,762 women are in need of subsidized family planning services.

The Family Planning Program in Oklahoma began in the late 1960s, with funding provided by the State of Oklahoma. In 1971, federal Title X legislation was adopted and since that time both federal and state funding has been used to support the program. Oklahoma, in the early years, had one of the highest per capita state-funded programs in the country. Since that time, however, state support has leveled and federal funding has decreased. In fact, from 1980 to 1990, Title X funding in the United States was cut 27% in actual dollars.

Unwanted childbearing has a high correlation with child abuse and neglect, poor health behaviors during pregnancy (including smoking, alcohol, and other substance use), late entry into prenatal care (leading to poor pregnancy outcome), and low birth weight. For further information about family planning in Oklahoma, you may contact your local health department or Tisha Webb, MD, Chief of Maternal and Infant Services, Oklahoma State Department of Health, (405) 271-4476.

Capsules

■ **Charles Funderburk, Jr., MD, Edmond, has** joined the practice of Sports Medicine Specialists and the active medical staff of Presbyterian Hospital's Oklahoma Center for Athletes. Dr. Funderburk earned his medical degree from the University of North Carolina School of Medicine and received fellowship training in orthopaedic sports medicine at the University of Oklahoma College of Medicine.

■ **Under the direction of George P. Hem-**street III, MD, Dr. Philip L. Jones and other researchers at OUHSC have developed a method that helps identify those at risk for bladder cancer, one of the often fatal "silent" cancers. Specifically, the team has developed technology to measure certain biochemical changes in bladder tissue, including excess DNA in call and elevated levels of certain proteins. The process involves the use of quantitative fluorescence image analysis (QFIA), a new technique developed by Dr. Hem-

In Memoriam

1992	
Ransom Francis Ringrose, MD	June 18
John L. Plewes, MD	June 21
David Lloyd Edwards, Sr., MD	June 23
Harlan Thomas, MD	June 30
Mark Donald Vanderslice, MD	July 13
William Branch Renfrow, MD	July 21
Jared Leigh Bryngelson, MD	August 14
Jo Ann Haynes, MD	August 14
Jack Allen Harder, MD	August 19
Kenneth Lee Peacher, MD	September 20
Antone Cosmo Fina, MD	September 25
Joseph Reid Henke, MD	September 28
Charles Morris Gunn, MD	October 10
George Caarreiro dos Santos, MD	October 12
John Graham, MD	November 10
John Frederick Kuhn, Jr., MD	November 11
Roy Willie Anderson, MD	December 8
Eugene Arthur Durso, MD	December 28
1993	
Howard Smotherman, MD	January 11
Robert Charles Mayfield, MD	January 9
Maud Staveley-O'Carroll, MD	January 16
David Lloyd Bell, MD	January 23
William Ray Turnbow, MD	February 28
Waldo B. Newell, Jr., MD	February 16
Homer Clark Wheeler, MD	February 18
William Alfred Waters, MD	March 19
William Niebuhr Weaver, MD	March 20
Willie George Long, MD	March 22
William Finis Ewing, Jr., MD	March 31
John Robert McInnis, MD	March 31
Chester Randall Seba, MD	April 4
Edward Cotter Murray, MD	April 9
Eric McLain White, MD	April 23
John Franklin DeJarnette, Jr., MD	May 1
Harold Alwin Smith, MD	May 4
Kenneth Warren Bonham, MD	May 28
John Raymond Stacy, MD	July 6
Carl Davis Osborn, MD	July 11
Mark Royal Johnson, MD	July 12
W. Turner Bynum, MD	July 13
James Dougherty Martin, MD	July 31
Horace Harold Porter, MD	August 15
Clifford A. Traverse, MD	August 20
J. Wendall Mercer, MD	September 2
Russell D. Harris, MD	September 28

Capsules (continued)

street. The research is profiled in the September 1 *Proceedings of the National Academy of Sciences.*

■ **PLICO loss prevention seminars will be conducted differently in 1994.** The seminars are being offered for sponsorship by county medical societies, to be held in conjunction with societies' regular meetings. Time blocks of approximately three hours are required. County societies wishing to host a seminar should contact Ed Kelsay at OSMA headquarters, 1-800-522-9452 or (405) 843-9571. PLICO also will sponsor a series of special purpose seminars.

■ **Donations are still being accepted by the OSMA** for the Mark R. Johnson Memorial Fund and should be directed to Executive Director David Bickham, OSMA, 601 Northwest Expressway, Oklahoma City, OK 73118.

■ **The JOURNAL is pleased to welcome a new cover** photographer this month, Dr. James S. Gerber of Okarche. The JOURNAL is always looking for new photo contributors. *Copies* of your favorite photos or slides, either color or black and white, should be directed to Managing Editor Susan Records, OSMA JOURNAL, at OSMA headquarters. Submissions should feature either medicine or Oklahoma scenes; vertical formats are preferred.

Deaths

Russell David Harris, MD
1904 - 1993

Russell D. Harris, MD, retired orthopedic surgeon and OSMA Life Member, died September 28, 1993. A native of Sherwood, North Dakota, Dr. Harris was graduated from the Washington University School of Medicine, St. Louis, in 1932. His postgraduate studies were completed in Oklahoma City, where he established his practice. During World War II he served on active duty with the U.S. Army for five years and held the rank of lieutenant colonel at the time of his discharge.

J. Wendall Mercer, MD
1899 - 1993

OSMA Life Member J. Wendall Mercer, MD, died in Tulsa on September 2, 1993. He was born near Lambert, Indian Territory, in 1899 and graduated from the University of Oklahoma Medical School in 1924. A general practitioner, he established his first medical practice in Cherokee, Okla., then moved to Enid in 1936. From 1942 to 1945 Dr. Mercer served in the U.S. Army Medical Corps, attaining the rank of major. After the war he returned to Enid and continued his practice until his retirement in 1971. Later he worked at Enid State Mental Hospital and the Garfield County Health Department before moving to Tulsa in 1986.

Clifford Austin Traverse, MD
1908 - 1993

Clifford A. Traverse, MD, died August 20, 1993, in Bedford, Texas, where he had moved afater his retirement. A native of Byron, Okla., he earned his medical degree from the University of Oklahoma Medical School in 1933. The following year was the first of his 35 years as a general practice "country doctor" in Alva. He then moved to Oklahoma City, where he spent almost four years with the Veterans Administration hospital before moving to Tenkiller and then Vian. Dr. Traverse was a Life Member of the OSMA. During World War II he served with the U.S. Armed Forces for a year, earning the rank of captain.

Classifieds

Classified ads are 50 cents a word, with a minimum of $25 per ad. A word is one or more characters bounded by spaces. Box numbers will be assigned upon request and will add 6 words to the total. Payment must accompany all submissions. **Orders will NOT be accepted via telephone or fax.** Mail ad with payment to OSMA JOURNAL, 601 Northwest Expressway, Oklahoma City, OK 73118. Deadline is the first of the month preceding the month of publication.

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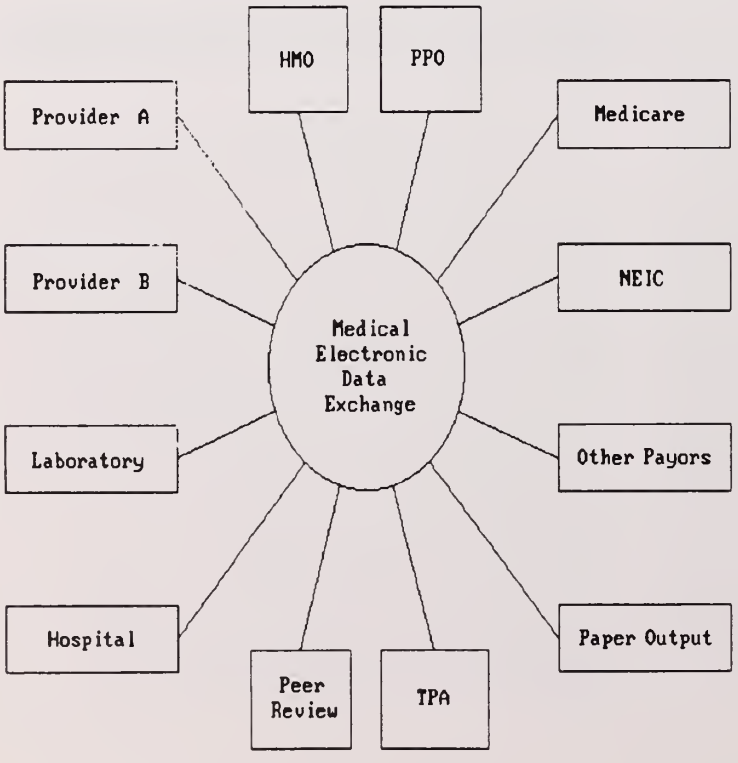
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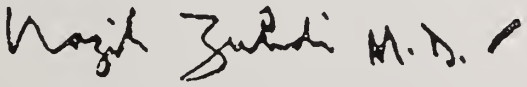
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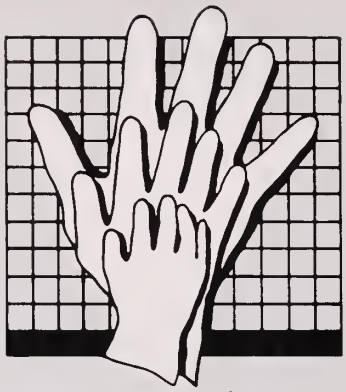
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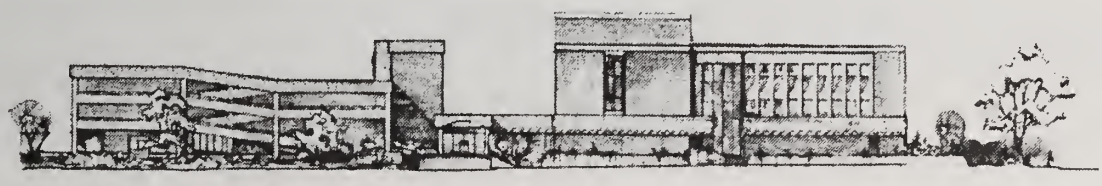
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All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style.* An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

Illustrations

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AUXILIARY

This year's plate is quite full for the auxilians in our state. One request that we have heard over the years is that auxilians "want to know more about what is going on regarding medical legislation," particularly in our state but also at our nation's capitol. Providing that information is definately a goal for this year. To start off, Legislation 101, a nuts and bolts session on how proposed legislation becomes law, was held on October 18 at OSMA headquarters. Thanks to Claudia Kamas, OSMA lobbyist, for giving generously of her time that day to make all of us better "lobbyists" for good medicine in Oklahoma. There's no reason now that any of us can't make our voices heard by our own legislators.

To coincide with OSMA President Lance Miller's new IMPACT program, we have over 50 auxilians signed up to be a part of this program at the grassroots level... that means ready to work in campaigns, talk to legislators, whatever is necessary to get medicine's message out and make an IMPACT on what the future of medicine will be. Those IMPACT auxilians will be receiving all legislative updates mailed out by the association while the legislature is in session so they will be well informed regarding proposed and pending legislation. It is critical that every county be ready to act when that action is necessary. ARE YOU A PART OF IMPACT?

To prepare auxilians and physicians to work in the 1994 campaigns of candidates willing to listen to medicine, the OSMA and OSMA Auxiliary are sponsoring an AMPAC Political Education Program on **WEDNESDAY, MARCH 2, 1994.** We will have professional political consultants from Washington to conduct this day-long seminar in Oklahoma City. Having attended a week-long school in Washington, I can tell you that this workshop will be excellent and a **MUST ATTEND** event for all doctors and auxilians who are considering working in campaigns and understanding more about the political process. You will be hearing much more about this event, but put **MARCH 2, 1994, 8:30 AM TO 4:30 PM** on your calendar today.

With health care reform the major issue at both the state and federal level, everyone in the medical family needs to be involved. There's no time to "let someone else do it" because the "wrong someones" will be in charge if we don't all take responsibility to be informed and to make that information available to those lawmakers who are deciding the fate of health care and the practice of medicine.

Will Rogers once said, "Even if you're on the right track, you'll get run over if you just sit there!" We in medicine will not be run over! Oklahoma auxilians are off to a good start, they're on the right track, and this year's plans don't call for much sitting around!

—Sherry S. Strebel, Chairman
Legislative Affairs

THE LAST WORD

■ **OSMA President G. Lance Miller, MD, and OSMA** Council of Government Activities Chairman Richard Boatsman, MD, led a delegation of seven Oklahoma physicians to Washington D.C., to attend the AMA National Political Education Conference September 29-30. The physicians met with members of the Oklahoma Congressional delegation to convey the OSMA's interest in the health care reform debate in Congress. Dr. Miller reported the delegation is sympathetic to the issues, particularly antitrust relief, the need for greater tort reform provisions, and the preservation of the physician/patient relationship.

■ **Donald K. Rahhal, MD, clinical professor of** obstetrics and gynecology at the University of Oklahoma Health Sciences Center (OUHSC) in Oklahoma City, has been appointed to a three-year term on the Council on Resident Education in Obstetrics and Gynecology. A 1971 graduate of the university, Dr. Rahhal is currently director of the American Board of Obstetrics & Gynecology.

■ **The AMA's Hospital Medical Staff Section will** hold its 22nd Assembly Meeting in New Orleans next month in conjunction with the AMA Interim Meeting. The HMSS gathering will be December 2-6, 1993, at the Hyatt Regency. Discussions will center on review and analysis of President Clinton's health care reform plan and the advantages and disadvantages of the organizational structures being created in response to federal, state, and business health care reform initiatives. For additional information, please call (312) 464-4745 or 464-4761.

■ **The presidents of Oklahoma's specialty societies** met September 15 in Oklahoma City with OSMA President G. Lance Miller, MD, and OSMA President-Elect Jay A. Gregory, MD. Dr. Miller presented the Health Access Oklahoma plan and discussed progress in forming the state provider network. Dr. Gregory urged the specialty society presidents to get more involved in the development of practice parameters for Oklahoma. The meeting proved so productive that plans have been made to conduct such meetings on a on a quarterly basis.

■ **The University of Oklahoma Health Sciences** Center is already taking steps to ensure it will survive the health care reforms proposed by the Clinton administration. Dr. Jay H. Stein, senior vice-president and provost, reports, "Primary care and rural health programs have been given priority for expanded support and development. Part of the primary care aspect recently was addressed with the installation of the Oklahoma Medical Information Network, or 'telemedicine' network, which will allow the state's rural practitioners to access our specialists via computer and participate in the two-way transfer of medical information and data." Other initiatives include integrating clinical departments into managed care programs and providing "attractive and affordable" service plans for patients.

■ **Dr. Roger A. Brumback, Oklahoma City, has** been elected to a two-year term as president of the Behavioral Neurology Society. The organization has led the effort to establish behavioral neurology as a specialty area of neurology. Dr. Brumback is professor of pathology at OUHSC and holds adjunct positions in the departments of Neurology, Pediatrics, and Psychiatry and Behavioral Sciences. He also is chief of the Pathology Department's Neuropathology Section.

■ **Theodore J. Brickner, Jr., MD, Tulsa, has been** appointed by Gov. David Walters to the Oklahoma Health Care Authority. The authority will be responsible for the "purchase (of) health benefits for state and education employees, Medicaid recipients, and others dependent on the state for necessary care." Among other things, the authority will "develop state and education employee benefit plans."

■ **The Oklahoma State Board of Medical Licen**sure and Supervision, in its August newsletter, reported the following disciplinary actions for the year July 1, 1992, through June 30, 1993: For drug/alcohol abuse—6 licenses suspended and then put on probation, 1 voluntary submittal to jurisdiction accepted for probation, and 1 physician assistant certification suspended; for sexual misconduct—1 license suspended; for excessive prescribing—2 licenses suspended and then placed on probation, 1 license suspended, 1 license placed on probation, and 2 licensees reprimanded; for conviction of a felony—1 license suspended for CHAMPUS fraud; and for violation of probation—2 licenses revoked and 1 license suspended (all three original probations resulted from drug/alcohol abuse).

Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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CONTRAINDICATIONS

Hypersensitivity to any component of this medication.

Active liver disease or unexplained, persistent elevations in liver function tests (see WARNINGS).

Pregnancy and lactation. Atherosclerosis is a chronic process and discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hypercholesterolemia. Cholesterol and other products of cholesterol biosynthesis are essential components for fetal development (including synthesis of steroids and cell membranes). Since HMG-CoA reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-CoA reductase inhibitors are contraindicated during pregnancy and in nursing mothers. **Pravastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.** If the patient becomes pregnant while taking this class of drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus.

WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhebdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondery to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; traume; severe metabolic, endocrine, or alectrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosponne. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occesionelly be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SQ 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SQ 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SQ 31,906 and SQ 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SQ 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli,* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells, a chromosomal aberration test in hamster cells, and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug:

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, penpheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma; anorexia, vomiting.

Reproductive. gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interections.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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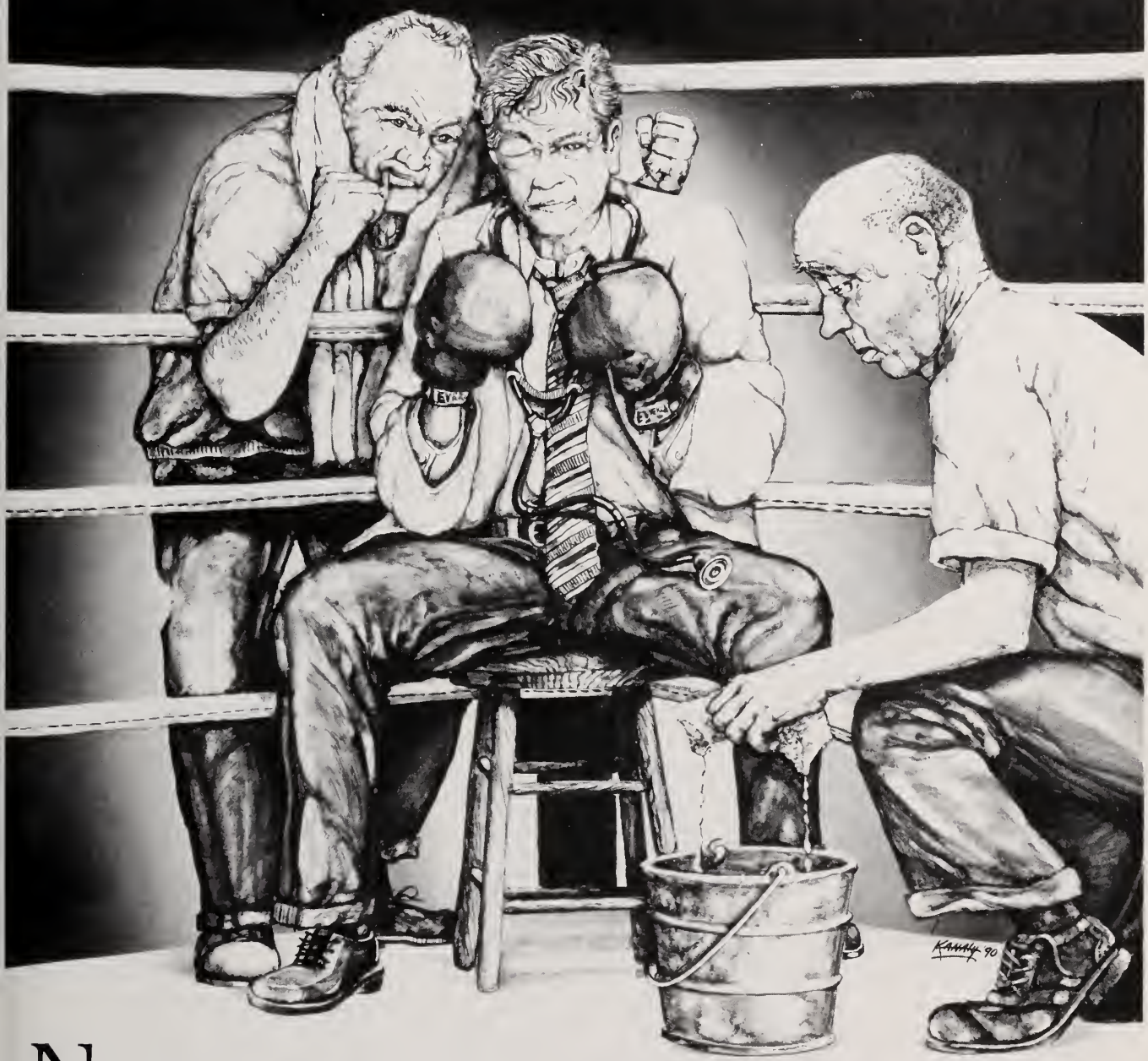
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ABOUT THE COVER

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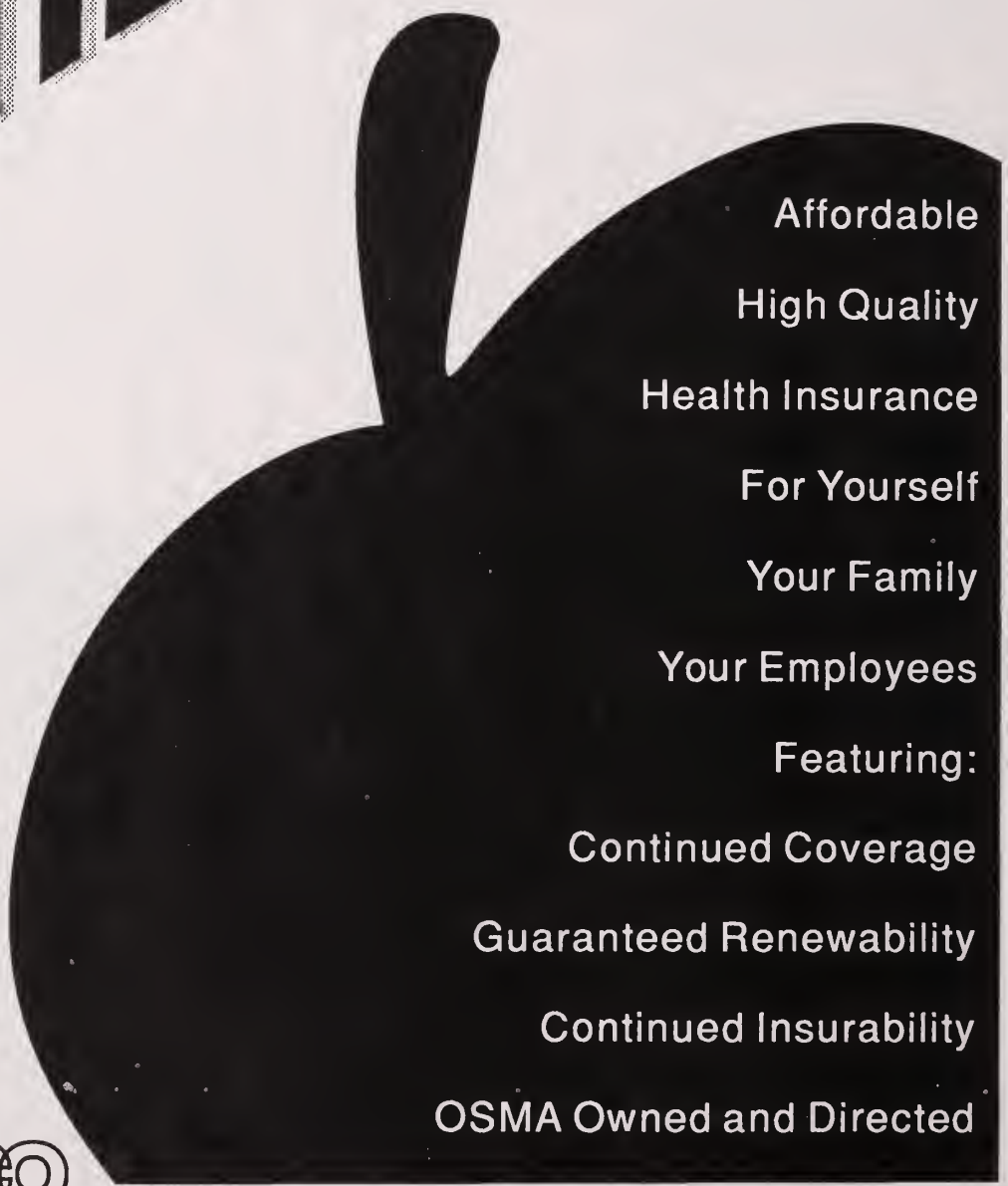
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Ray V. McIntyre, MD

The Unbroken Circle

On occasion we are able to revisit the past. We may tour a living history village, peer into a time capsule, or read an account of how things once were. As we commune with the essence of an olden time, we are offered a lesson in both fact and feeling. Historical events are given human meaning and context. We may feel the tribulations and the accomplishments of our forefathers in a new way. With luck, we also derive a keener insight into the relative importance of the problems our own generation now struggles to solve.

Dr. Anspaugh's reminiscences on Oklahoma City obstetrics and gynecology on page 626 of this issue opens such a time capsule to the readers.

Younger physicians may acquire a new awareness of problems that have been solved and develop a new understanding of the strength of the shoulders upon which they stand. This heightened consciousness may then result in a renewed commitment to unriddle current dilemmas. We hope that an increased awareness of the values of the past will encourage a reanimation of the altruistic passion that originally brought most physicians into medicine. A keen appreciation of the past can increase the accomplishment potential of those presently laboring with the odious problems in today's medicine.

The older physician reader not only may be reminded of how things were, but will see again the significant medical achievements of the generation now hanging up their stethoscopes. The remembrance of completed challenges may well solace the decadent feelings of the sunset years.

It has ever been, regardless of profession, that living life is adapting to, solving, or overcoming successive problems. The educational experiences taught us by our patients and our teachers and our mentors are our invaluable adaption tools. But the understanding of the difference in the permanent and the temporary elements of medical practice that we gain from Dr. Anspaugh's reminiscences is another valuable lesson.

Over the years there is a common theme to the work of the physician. While the technical tools of the profession are variable from time to place to specialty, there is an unbroken circle of caring and human warmth and support that is endless and is the reason for the physician's existence. The lesson of patient caring is the greatest lesson the teacher physician must transfer to the student physician.

Ray V. McIntyre, M.D.

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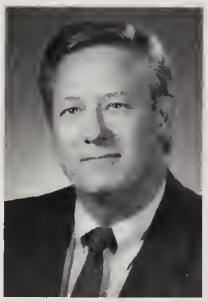
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President's Page

G. Lance Miller, MD

Condition: Critical



I have failed you—and I'm truly sorry.

Recently I've developed a sense of inadequacy, of inability to provide acceptable leadership to you, the members of this fine and respected association.

I'm pleased with my efforts to guide your leadership in developing strategies and programs which surely will position all of us to best control our futures—for example, an expanded political activities program (IMPACT), a sensible health care reform plan for our state, and perhaps most critical, the development of a physician-owned statewide insurance network.

Yet despite these efforts, I feel I have fallen short as your president. The single most important quality of a leader is to be a good communicator, and in this endeavor I seem to have failed.

I've been unable to convince the majority of our members that these programs represent perhaps the most important issues ever to affect physicians and that they can provide immeasurable benefits to us all.

After considerable effort by many members to develop our reform plan and the insurance network, the leadership and staff fanned out through the state, conducting numerous meetings to explain these programs.

Toward the end of this hectic schedule, reality began to set in. The result? Less than twenty percent of our members understood the importance of these issues and/or the importance of learning about them.

I've tried the rationalization of blaming the "ostrich syndrome," so prevalent among physicians, but in reality I have only myself to blame.

These are not normal times—these are exceptional times, and exceptional measures are necessary. Unfortunately, I have not found an exceptional formula for communicating to you the critical nature of these issues.

I apologize.

Oh, and by the way... Happy Holidays.

G Lance Miller, MD



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Allogeneic Bone Marrow Transplantation: Experience with 92 Patients

George B. Selby, MD; Ruben A. Saez, MD; Robert B. Epstein, MD;
R. Bradley Slease, MD; Dennis L. Confer, MD

Allogeneic bone marrow transplantation (BMT) is potentially curative therapy for leukemia, lymphoma, and marrow failure. Ninety-two patients have received allogeneic BMT at Oklahoma Memorial Hospital in the past 10 years. Patients with acute myelogenous leukemia (AML; *N*=30), chronic myelogenous leukemia (CML; *N*=27), acute lymphoblastic leukemia (ALL; *N*=12), myelodysplastic syndromes (MDS; *N*=8), lymphomas (*N*=8), and aplastic anemia (*N*=7) were treated with a variety of myeloablative preparative regimens. The major causes of mortality were bacterial, viral, and fungal infections, or disease relapse. Standard and high risk (refractory or multiply-relapsed disease) AML, CML, and ALL patients had median survivals of 14.5 months vs. 3 months, >18 months vs. 9 months, and 10 months vs. 4.5 months (p=0.01), respectively. At 7.5 years median follow-up, 71% of the aplastic anemia patients are disease-free. Guidelines for the optimal time for BMT have been developed that encourage transplantation earlier in the course of the disease, thus facilitating better outcomes with these otherwise fatal disorders.

OVER THE PAST 25 YEARS, BONE MARROW TRANPLANTation (BMT) has progressed from a last desperate effort to cure the incurable, to a successful first-line therapy that is curative for acute and chronic leukemia, severe aplastic anemia, myelodysplasia and lymphoproliferative disorders.[1] Improved outcomes with BMT have resulted from its utilization before the patient has developed resistant disease or serious treatment-related toxicities.[2] The underlying principle of allogeneic bone marrow transplantation is simple: sublethal doses of radiation and/or chemotherapy are employed to eradicate diseased tissue and marrow, followed immediately by the intravenous administration of matched-donor, bone marrow-derived hematopoietic stem cells that replace and reconstitute the patient's hematologic and immune systems.

Autologous bone marrow transplantation employs the same treatment strategies but utilizes the patient's own marrow, thereby circumventing the risk of graft-versus-host disease (GVHD). Despite the intrinsic risks of infections, drug toxicities, GVHD (with allogeneic BMT), and even death, the applicability of BMT as an effective therapy continues to broaden. Our experience with BMT dates from 1982 and includes 348 patients. The current paper reports the 92 allogeneic BMT patients transplanted for leukemia, marrow failure, or lymphoma.

Methods and Materials

Fifty-nine males and 33 females received allogeneic BMT between September 1982 and December 1992. The mean age of transplant patients was 31.5 years (range: 11-58 years). Patients treated for acute myelogenous leukemia (AML) were transplanted either in first complete remission (*N*=15) or in second or third complete remission, relapse, or after failure of primary induction therapy (*N*=15). Transplantation for chronic myelogenous leukemia (CML) was done in the first chronic phase (*N*=19) or during accelerated, blastic, or second chronic phases (*N*=8). Acute lymphoblastic leukemia (ALL) was

Direct correspondence to George Selby, MD, College of Medicine, Department of Medicine, PO Box 26901, Oklahoma City, OK 73190.

transplanted seven times in first or second complete remission and five times with either refractory disease or later-than-second remission. All Hodgkin's Disease (HD, N=4) and Non-Hodgkin's Lymphoma (NHL, N=4) patients had either relapsed and/or refractory disease. Eight patients with myelodysplastic syndrome (MDS) and seven with severe aplastic anemia (SAA) were transplanted.

Donors were appropriately human leukocyte antigen (HLA)-matched sibling donors (N=82) or HLA-matched unrelated donors (N=10). Tissue typing was performed as previously described.[3] Unrelated donors were utilized once in AML, HD, ALL, and MDS, twice for SAA, and four times for CML. Under general anesthesia, bone marrow was aspirated from both posterior iliac crests of the donor and, rarely, from the anterior iliac crest if additional marrow was required. The aspirate was then passed through stainless steel screens to remove clots and small bone fragments as described elsewhere.[4]

Transplant recipients were prepared with cyclophosphamide/total body irradiation (N=32); busulfan/cyclophosphamide (N=46); etoposide/total body irradiation (N=8); cyclophosphamide/antithymocyte globulin (N=2); cyclophosphamide alone (N=2); cyclophosphamide/etoposide/total body irradiation (N=1); or cyclophosphamide/BCNU/etoposide (N=1). Following completion of the preparative regimens, the donor's marrow was infused into the recipient through a right atrial catheter.

Infection prophylaxis procedures have evolved over the years, but all patients received trimethoprim/sulfamethoxazole pneumocystis prophylaxis and most patients were treated in laminar airflow rooms while receiving fluoroquinoline antibiotics and fluconazole. Broad spectrum parenteral antibiotics were eventually required for 95% of the recipients. All patients were supported with parenteral nutrition as well as erythrocyte and platelet transfusions.

Cyclosporine A, methotrexate, and corticosteroids were used to prevent and treat acute and chronic graft-versus-host disease (GVHD). Grading of GVHD followed the guidelines of Glucksberg et al[5] and the International Bone Marrow Transplant Registry.[6]

Results

A mean of 3.12×10^8 mononuclear cells/Kg of recipient weight were infused (range $1.55\text{-}7.29 \times 10^8$). Median time to absolute granulocyte count greater than 500/m^3 was 19 days and recovery of platelets greater than 50,000/mm^3 was 32 days. The average length of hospital stay for patients discharged alive was 39 days (range 25-68 days). The major causes of mortality were disease relapse (N=13), bacterial infection (N=12), cytomegalovirus pneumonia (N=7), hepatic veno-occlusive disease (N=7) and aspergillosis (N=6). Other etiologies accounted for an additional seven deaths (Table 1). Patients at standard (N=41) or high risk (N=28) for relapse and/or death were defined for AML, CML, and ALL (Figs. 1-3). Analysis by the Mantel-Haenszel test showed a significant relapse-free survival advantage (p=0.01) for the standard risk group.

Acute Myelogenous Leukemia. The patients transplanted in first remission have an actuarial relapse free survival (RFS) of 37% at 80 months and a median RFS of 14.5 months (Fig. 1). If transplanted in other than first remission, the median RFS is 3 months, with an actuarial RFS of 20% at 80 months. The median follow-up of survivors is 5 years. Acute graft versus host disease of Grade II (more than mild skin rash) or worse occurred in 12 patients. Eleven of the 23 patients surviving at least 100 days post-transplant had more than limited (skin only) chronic GVHD.

Chronic Myelogenous Leukemia. Those patients treated in first chronic phase have not yet reached their median RFS (Fig. 2). Actuarial RFS survival is 65% at 50 months. Median RFS for non-chronic phase patients

Table 1. Causes of Death After Bone Marrow Transplantation

	AML	CML	ALL	HD	NHL	SAA	MDS	Total
Relapse	5	3	3	1	1			13
Bacterial Sepsis or Pneumonia	4	2	2	1		1	2	12
Cytomegalovirus Pneumonia	3	2					2	7
Hepatic Veno-occlusive Disease	3	2		1			1	7
Aspergillosis	1	1		1		1	2	6
Pulmonary Fibrosis	1		1					2
Acute GVHD*	1				1			2
Acute Respiratory Failure	1							1
Torulopsis Fungemia	1							1
Congestive Heart Failure					1			1

AML = acute myelogenous leukemia, **CML** = chronic myelogenous leukemia, **ALL** = acute lymphoblastic leukemia, **HD** = Hodgkin's disease, **NHL** = Non-Hodgkin's lymphoma, **SAA** = severe aplastic anemia, **MDS** = myelodysplastic syndrome
*GVHD = graft-versus-host disease

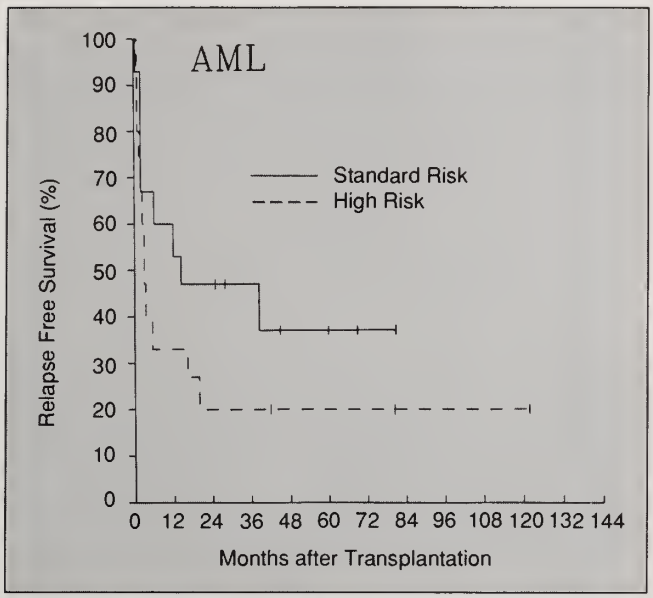


Figure 1. Actuarial Relapse-free survival following BMT of Standard Risk (first remission, *N*=15) or High Risk (After first remission, refractory, or in relapse, *N*=15) AML patients.

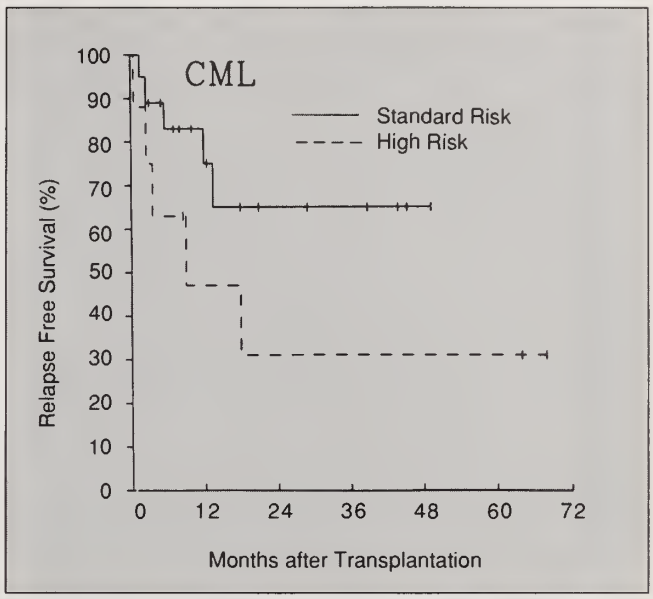


Figure 2. Actuarial Relapse-free survival following BMT of Standard Risk (first chronic phase, *N*=19) and High Risk (accelerated, blastic, or second chronic phase, *N*=8) CML patients.

was 9 months, with an actuarial RFS of 31% at 50 months. Surviving patients have a median follow-up of 18 months. Twelve patients developed acute GVHD of Grade II or worse and 6 of 13 one-hundred-day survivors have extensive chronic GVHD.

Acute Lymphocytic Leukemia. Patients transplanted in first or second remission have a median RFS of 10 months and an actuarial RFS of 48% at 3 years (Fig. 3). Patients transplanted in other than first or second remission had a median RFS of 4.5 months. The survivors have a median follow-up of 31 months. Ten of the 12 patients developed Grade II or worse acute GVHD and 5 of the 8 one-hundred-day survivors have extensive chronic GVHD.

Aplastic Anemia. Forty-five months is the median follow-up of survivors and the median survival has not been reached with an actuarial RFS of 71% at 7.5 years. There have been no relapses of aplastic anemia (Fig. 4). Acute GVHD exceeded Grade II in 2 patients and 2 developed extensive chronic GVHD.

Myelodysplastic Syndrome. There is one disease-free survivor 33 months post-transplant (Fig. 4). All other patients died within 4 months of transplantation. Acute GVHD developed in four patients of Grade II or greater, and the single survivor has limited chronic GVHD.

Hodgkin's Disease (HD) and Non-Hodgkin's Lymphoma (NHL). One NHL patient with a syngeneic transplant (identical twin donor) is alive disease-free 8

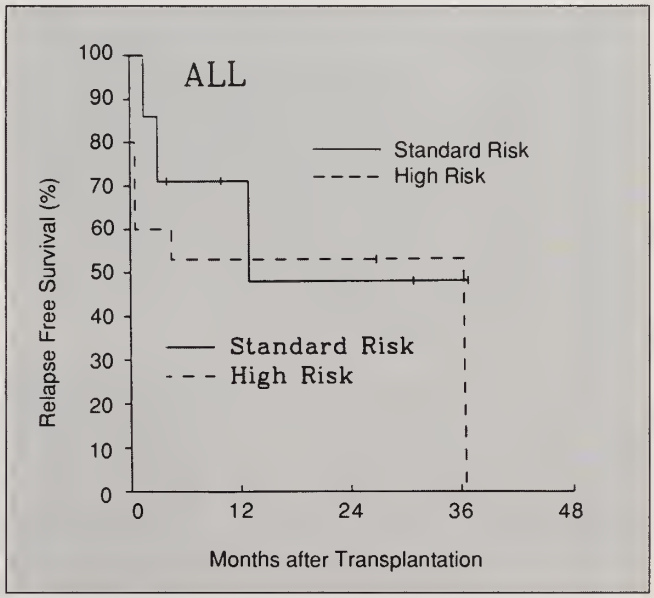


Figure 3. Actuarial Relapse-free survival following BMT of Standard Risk (first or second remission, *N*=7) or High Risk (Other than first or second remission, *N*=5) ALL patients.

years after transplantation. The other three NHL patients died within 3 months of transplantation, including one death caused by progressive disease. One patient developed Grade IV acute GVHD. All of the HD and NHL patients were heavily pretreated after multiple relapses of their disease, and all succumbed to either

transplant-related morbidity (N=5) or disease relapse (N=2) within 3 months of BMT.

Discussion

Allogeneic BMT is potentially curative for CML, AML, ALL, lymphoproliferative disorders, MDS, and aplastic anemia. Significant progress has been made in the prophylaxis and treatment of bacterial, viral, and fungal infections in the 10 years spanned by this series. Progress has been less remarkable in decreasing the incidence of disease relapse or the development of GVHD. A variety of preparative routines have been developed to address the problem of relapse, but none has proved to be markedly superior to the regimens of a decade ago.[7-9] In contrast to solid organ transplants, graft rejection is a relatively minor problem in bone marrow transplants. Rather, donor marrow-derived activated T-lymphocytes attempt to "reject" the recipient, resulting in GVHD. The addition of cyclosporine A to methotrexate and corticosteroids in the early 1980s provided what still remains the cornerstone of GVHD prophylaxis and treatment.[10,11] While marrow purging, monoclonal antibodies, and new pharmacologic agents offer promise in the management of GVHD, they have yet to withstand the rigors of prospective randomized trials and become standard treatment. The survival results reported in this series are comparable to other groups including the International Bone Marrow Transplant Registry.[12] In ours, as in other series,[13] acute and chronic GVHD remain a major source of morbidity with incidences of 45% and 49%, respectively, but only three patients have been unable to return to their pretransplant vocations at least part-time.

The strongest conclusion from these data is that the window of opportunity for successful BMT is early in the course of the disease. To delay transplantation is to risk hitting the wall of peritransplant morbidity and mortality. Appropriately selecting patients is of paramount importance, and the treatment of multiply relapsed, refractory diseases yields dismal results. With this in mind, we have adopted the guidelines summarized in Table 2 for the consideration of patients for allogeneic BMT. Adults younger than 55 years in their first remission of AML or ALL with an appropriate donor should be evaluated for BMT. Children in first remission AML should also receive serious consideration for BMT. The role of BMT in childhood ALL continues to evolve as the identification of poor prognostic factors allows the selection of youngsters that should receive BMT in first remission, rather than the traditional strategy of waiting until relapse to consider BMT. While chronic phase CML may have a relatively benign course for several years, all patients eventually succumb to CML. Their outlook following BMT is much brighter if it is undertaken within a year of diagnosis and before disease accel-

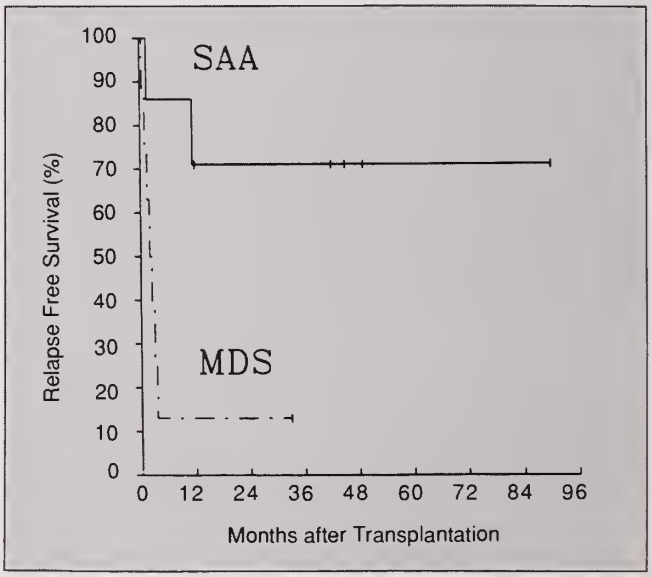


Figure 4. Actuarial Relapse-free survival of severe aplastic anemia (SAA) patients (N=7) and myelodysplasia (MDS) patients (N=8).

Table 2. Guidelines for Optimal Allogenic Bone Marrow Transplantation Consideration

Disease	Disease Status
Adult acute myelogenous leukemia (> 18 years, < 55 years)	First remission Induction failure
Childhood acute myelogenous leukemia	First remission Induction failure
Adult acute lymphoblastic leukemia (> 18 years, < 55 years)	First remission Induction failure
Childhood acute lymphoblastic leukemia	Second remission Poor prognosis first remission Induction failure
Aplastic anemia	Primary therapy if donor available Immune modulation failure
Hodgkin's disease or Non-Hodgkin's lymphoma	Not an autologous bone marrow transplant candidate First relapse following combination chemotherapy Induction failure
Myelodysplastic syndrome (< 60 years old)	Poor prognostic morphology or chromosomal abnormalities

eration or transformation occurs.[12] Myelodysplastic syndromes are more common in older people, but when encountered before the age of 60, BMT may be appropriate—being mindful that the tempo of MDS is widely variable and that appropriate therapy for a 30-year-old may differ from that for a 60-year-old. Despite the availability of more effective immune modulating therapy for SAA, such as antithymocyte globulin and cyclosporine A, BMT remains the treatment of choice when a matched, sibling donor is available.[14] Allogeneic BMT for Hodgkin's disease and Non-Hodgkin's lymphoma should only be done when marrow disease precludes an autologous BMT. Utilizing this strategy, lymphoproliferative diseases potentially have 40% long-term survivors if the transplant is performed before multiple relapses have transpired.[15,16]

With greater insight into early appropriate patient selection, continued improvement in BMT supportive care, progress in combating GVHD, better preparative regimens, the development of gene insertion therapy, and greater use of matched unrelated donors,[17] the next 10 years promise to provide further successful applications of BMT to hematologic and immunologic disorders.

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Stereotactically Guided Needle Biopsy of the Breast for Nonpalpable Lesions

Jay A. Harolds, MD

Stereotactically guided needle biopsy of the breast is a new diagnostic technique in this country to obtain samples of a nonpalpable area deemed suspicious for malignancy on mammography. This article is a review of the literature, a report of a case, and a description of the technique. This procedure, when performed with a large core biopsy needle, appears to be about as accurate as surgical biopsy.

STEREOTACTICALLY GUIDED NEEDLE BIOPSY OF THE breast is a new diagnostic technique in this country to obtain samples of a nonpalpable area deemed suspicious for malignancy on mammography. However, it has been used for many years in Europe and is described in several papers.[1-4] A review of the experience of many centers demonstrates 11% to 36% of surgical biopsies are positive for malignancy when the surgical biopsy is recommended on the basis of mammographic findings alone.[5]

One of the reasons women are reluctant to participate in mammographic screening is that the vast majority of the time, when an open biopsy is recommended, the lesion is benign and they are left with the pain, cost, scar, and occasional deformity of the surgery. It has been estimated that if all women followed the American Cancer Society screening guidelines, over one million biopsies would be done annually in this country.[5]

If stereotactic biopsy can reduce the number of surgical procedures for benign lesions and not have a significant cancer miss rate, it will be a major advance. Furthermore, women may then be more amenable to participation in screening programs,[6-8] with a resultant reduction in breast cancer mortality.

Types of Equipment

Currently two major classes of stereotactic devices are approved by the Food and Drug Administration (FDA). The first is a small and relatively inexpensive add-on device that attaches to a standard mammography unit. With this unit, the procedure is performed with the patient upright. The second device, introduced in Sweden in the late 1970s and in the U.S. in 1986, is a dedicated biopsy unit in which the patient lies prone on a specially built padded table. The breast to be biopsied protrudes through an aperture on the table. Women are more likely to have a syncopal episode during the procedure with the add-on unit rather than the prone unit.[9] The prone unit is more comfortable for most women, and there is less patient movement. It is much more expensive than the add-on device, and a larger room is usually needed for it. Adequacy of some of the specimens obtained on the add-on units tends to be lower than on dedicated prone units.[9,10] However, in a small percent of patients, the upright unit may be superior if the patient can remain still. This includes those who cannot assume a prone position, severely kyphotic individuals, and lesions in the axilla.[11] The FDA has recently approved a 1024×1024 digital TV display which can be added onto the prone units. The TV images are excellent and shorten the procedure considerably since one does not need

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to keep developing films. However, the TV option is expensive.

Stereotactic Biopsy Procedure

Before the biopsy is started, the stereotactic unit is calibrated with a phantom to confirm accuracy. The physician discusses the procedure with the patient and informed consent is obtained. After reviewing the mammograms, an approach is selected that offers the shortest possible distance from the needle insertion point to the lesion. The patient's breast is positioned in the unit. For the prone unit, great care is taken to put foam wedges under the patient's pressure points, both for the patient's comfort and to help her to remain still during the procedure.

During the procedure, with either unit, a 15° tube and cassette shift is made, first to one side and then the other. The resultant stereo radiographs are therefore 30° apart. With a special computer program, one can determine the X, Y, and Z coordinates of the lesion in the the breast to within one millimeter. The skin is then cleansed with alcohol or Betadine. One cubic centimeter of 2% xylocaine is injected intradermally, with the option of giving another 1 cc along the intended needle track. It is important not to give too much xylocaine since this could obscure the lesion and also possibly change its relative position.[11] Xylocaine injected directly into the lesion may also obscure critical findings for the pathologist, particularly with cytologic studies.[12]

The skin is then nicked with a scalpel. The needle is then inserted and positioned. One can then do either an aspiration biopsy with a 21- or 22-gauge needle or obtain a core biopsy, usually with a 14-gauge needle. Also note that the Z plane setting on the machine is set differently depending on whether a core biopsy or fine-needle aspiration (FNA) biopsy is used. This is because the first few millimeters of the core biopsy needle do not obtain tissue, i.e., the slot is several millimeters posterior to the needle tip. However, there is no such dead space in an FNA needle. It is important with the FNA technique to make sure the needle tip will go through and then beyond the precise target.[11,13]

For both techniques, one to eight biopsies are taken in various portions of the lesion.[9,11,14] The FNA requires that 5 to 7 cc of negative pressure is applied with a 10 to 20 cc syringe while the needle is in the lesion and that the pressure slowly be released before the needle is withdrawn.[11,13] A syringe holder can be helpful. Furthermore, with each aspiration 5 to 20 strokes of the FNA needle are done at different angles varying by about three degrees.[11,13,15] Hewett recommends staying in the lesion with the needle tip as much as possible and not moving the tip more than a few millimeters[2,3] to either side of the lesion.[12] A greater proportion of the lesion is sampled with one fine needle aspiration than one core biopsy.[10]

For at least one biopsy, the needle tip position is documented on an image. This is to ensure that the needle did not bend away from the lesion, which is more likely with a fine gauge needle, and that the patient did not move. For core biopsy, a post firing position image of the needle is also documented.[9]

Patient discomfort during the procedure is greater with the aspiration technique, but discomfort after the procedure is greater with the core biopsy technique.[11] Patient discomfort during the procedure is minor, with the major complaint being related to the discomfort of being in one position for 40 to 60 minutes. Afterwards, there may be some minor pain and swelling in the breast. The woman is not restricted in her activities.

Indications for Use

There are several different settings in which stereotactic biopsies may be helpful. If one believes a lesion is strongly suspicious for malignancy, and the biopsy shows breast cancer, then if a mastectomy is indicated, this can be done without prior excisional biopsy.[14] If the stereotactic biopsy is negative but there is a strong suspicion of carcinoma, then depending on the indication, a follow-up stereotactic biopsy, open surgical biopsy, or mammographic follow-up at 4 to 6, 12, 24, and 36 months is done unless there is a change in the lesion. If a lesion is slightly suspicious for malignancy on mammography and the stereotactic biopsy is negative, then follow-up mammography at 6, 12, 24, and 36 months may be done.

In a large study of the follow-up of lesions diagnosed as having a very low probability of being malignant,[16] only 0.5% turned out to be cancerous. Furthermore, in a median follow-up time of five years, none of these patients with carcinoma of the breast had known recurrence of the tumor. In another series,[17] only nine of 558 nonpalpable, probably benign lesions were found to be due to carcinoma. Characteristically benign lesions were not considered in these figures. These papers indicate that lesions fitting the category of being probably benign can be followed, and not subjected to surgical biopsy immediately, unless there are clinical, including psychological, reasons to do otherwise.

The presence of a stereotactic unit in the community allows a physician and patient to have a wider choice between a surgical biopsy and a six-month interval of worry before a follow-up exam. The total cost of the stereotactic biopsy at our institution is about half or less than the typical total charge for surgical biopsy. Also, there is no need for an anesthesiologist. There is no scar,

no breast deformity, and no significant morbidity from the stereotactic biopsy. This is in contrast to the surgical procedure. In a series of over 500 procedures done at the University of Arizona, there were no infections.[11] In another series of over 1,000 patients from Denver, there were also no infections.[18] This is another advantage over the open biopsy.

Another use of the stereotactic unit is needle localization prior to surgical biopsy. In most cases, the use of the unit for this purpose is unnecessary, and in some cases the surgeon may not prefer the entrance of a needle far from the periareolar area. However, occasionally a lesion is difficult to visualize except in one plane, but oblique and spot compression views confirm that the lesion is real and not due to a fortuitous summation of physiologic shadows. Under these circumstances, the stereotactic unit is very useful to localize the area of concern for the surgeon. Use of the prone unit for localization will probably increase as digital mammography becomes more available. The procedure time is shortened and there is less discomfort for the patient.

Occasionally, cyst aspiration and injection of air (pneumocystography) is done under stereotactic guidance. If ultrasound demonstrates a classic simple cyst, nothing further needs to be done. Exceptions include cases in which either the cyst is painful or large, and there is concern that it could obscure an adjacent carcinoma.[11,19,20] Masses not fulfilling all the criteria of a simple cyst on ultrasound may require localization. In those cases, aspiration could be done using ultrasound guidance, followed, if necessary, by pneumocystography. Cystic lesions difficult to visualize on ultrasound due to considerable depth or small size, may be aspirated using the stereotactic device. If it is not a cyst, biopsy may be done.

It is not necessary to use the stereotactic method on large, superficial, palpable masses. Palpable masses may still be biopsied by needle, but radiographic guidance is not always needed. Also, extremely superficial lesions are best biopsied by other means.[9] If a very small lesion is within a few millimeters of a breast implant, it may not be possible to adequately sample it by the stereotactic method.

If a breast compresses to 2 cm or less, then it may be difficult or impossible to biopsy with a long throw core biopsy gun as the needle excursion is 22 to 23 mm. Short throw core biopsy guns are available, but are not recommended because of poor samples. A locking suction syringe and core needle set is available to be used with extremely thin breasts.

Finally, if a specimen is clinically felt to be needed for a very large lesion or for a diffuse, ill-defined area of increased density, or for an area of architectural distortion without a distinct mass, or to evaluate a possible radial scar identified on mammography, then a surgical biopsy is suggested.[11] Nevertheless, most masses or areas of suspicious calcifications seen on mammography are amenable to biopsy with this technique using either core biopsy or FNA.

Core Biopsy vs. FNA of the Breast

A. Fine Needle Aspiration. The controversy over whether to use core biopsy or FNA has not been resolved. FNA has been used to diagnose breast cancer for over half a century. Franzen and Zajcek[21] reviewed 33 articles published between 1933 and 1967 with respect to FNA of palpable breast lesions. By 1968, FNA use was generally felt to be indicated to decide whether a mass was due to carcinoma or benign inflammation, to diagnose non-surgical cases prior to radiation therapy, and to puncture suspected cysts. Today, FNA is widely used in many centers for virtually all palpable breast masses. Furthermore, in some institutions, especially in Europe, it is used for stereotactic biopsy.

Despite its popularity, problems can and do occur with FNA. In my review of numerous breast FNA articles,[2,5,7,8,14,15,21-49] I found widely different results. For example, false positive results of 0 to 11% and false negative results of 0 to 49% have been reported in a review by Layfield.[22] A criticism of breast FNA is sample inadequacy. In five different articles on breast FNA, the percentage of inadequate FNA aspirates ranged from 3 to 54%![33,43-46]

The incidence of unsatisfactory FNA biopsies for nonpalpable lesions is such that some authors recommend an expert cytopathologist be present to examine the aspirate before the study is concluded.[11,50] The average false negative rate for malignancy in 12 articles on breast FNA biopsy was 10%.[14]

However, very good results have been reported in a number of recent papers. Malberger reported zero false negatives and a 1.7% inadequate specimen rate for breast FNA.[25] In another paper, the sensitivity was 93% and the specificity was 97% for finding breast cancer with FNA.[24] Dowlatshahi et al[37] reported on over 400 cases in which stereotactic biopsy results were compared to surgical open biopsy results, finding there were no occasions in which a lesion measuring at least 1 cm in diameter had a false negative stereotactic result. Gent[40] reported that with a prone stereotactic device he had a sensitivity of 97.5% and a specificity of 95.2%. The FNA was followed by surgery in his 187 cases. Ciatto found a sensitivity of 83.8% and a specificity

of 96.6% with stereotactically guided FNA in a one year follow-up.[51]

To explain this variability, the importance of operator experience has been emphasized.[37,47] Dixon compared FNA performed by multiple different physicians of varying skill levels to one physician expert in performing the procedure. The accuracy of finding malignancy went from 59% to 99%.[48] Similarly, Lee[49] found the inadequate sample rate went from 45.9% with multiple individuals of varying expertise performing FNA to 9.8% when one expert did the aspirations. If one has an expert performing FNA and can consult an expert cytopathologist regarding the adequacy of the aspirate before the patient is dismissed, then the number of inadequate samples should be low. However, it has been found that some tumor types and cystic lesions may yield insufficient cells for diagnosis.[22,42]

Cytopathologic interpretive errors can also occur. A false positive diagnosis of malignancy was made in one case in a series of 114 FNA breast biopsies, but a repeat reading indicated benignancy.[28] In another series of 215 breast FNA biopsies, one carcinoma was misdiagnosed as being a fibroadenoma.[33]

Finally, if there is a problem with needle localization, this should be communicated in the report.

With these precautions, satisfactory results can be obtained with FNA. However, the variability of results has led many to advocate the 14-gauge core biopsy for nonpalpable lesions.

B. Core Biopsy. Elvecrog[52] reported on a study of 75 women who had nonpalpable, suspicious breast lesions at least 5 mm in diameter on mammography. These patients first had 14-gauge needle biopsies done stereotactically, and then had surgical biopsy. Two fibroadenomas and one malignancy were missed by core biopsy. The latter malignancy was manifested by a 2 to 3 mm wide band of microcalcifications.[53] Surgery missed one fibroadenoma and one malignancy. The authors concluded that stereotactic core biopsy and surgical biopsy had the same accuracy for diagnosing cancer of the breast.[52,53] The series now has 100 patients and there still has been only one miss by core biopsy.[53]

Dr. Parker has been an advocate of core biopsies obtained with a biopsy gun rather than FNA for years.[54] One of these studies reported on 102 patients with nonpalpable lesions that were suspicious for malignancy.[55] Each first had 14-gauge core biopsies with a biopsy gun, followed by localization and biopsy. Cancer was found in 23 patients, 22 made by needle biopsy. One case of infiltrating ductal carcinoma was missed by the needle biopsy because the needle was close, but not in the lesion. The latter lesion was close to the chest wall and much retraction of the breast was required to try to biopsy the area. All the cancers were found at surgery; however, some benign lesions found at stereotactic biopsy were missed at surgery.

This 2% miss rate at needle biopsy is a considerable improvement since a prior series with 103 patients[56] in which there was a 9% false negative rate with various sized needles and types of equipment. However, the researcher had only a 3% false negative rate with a 14-gauge needle and a dedicated stereotactic unit on the last 29 biopsies. The first 74 biopsies were done with 18- or 16-gauge needles. Obviously, he also had greater experience in the final group of patients.

In another case, an area of lobular carcinoma in situ found at surgical biopsy and not at core biopsy was remote from the lesion seen at mammography. Such serendipitous findings will probably always make core biopsies and FNA biopsies seem to be less accurate than they are. In one case, a cancer found at core biopsy was missed at open biopsy. At repeat surgery, the malignancy was found. Several papers have reported that surgeons do not initially remove a suspicious nonpalpable lesion 2 to 10% of the time.[6,8,57,58] In two recent studies, the miss rate at surgical biopsy despite preoperative localization was 2.1 to 2.5%.[59,60] This has caused Dr. Parker to remark that the miss rate of surgical biopsy and stereotactic core biopsy is similar in his institution.[18] Dr. Fajardo has also had the experience of having a diagnosis of malignancy made at core biopsy and then the lesion was missed on the initial open biopsy but found at follow-up surgery.[11]

Of 250 stereotactic 14-gauge core biopsies of the breast performed at the Baylor Komen Breast Center of Dallas,[61] 44 had a diagnosis of malignancy, and all of these lesions were proven to be malignant. There were only 3 cases with inadequate samples, and all were found to be malignant at surgery. Twenty-one patients felt to have benign lesions were operated on anyway and all lesions were benign. Follow-up mammography for an average of about a year showed no alarming change in the other cases. At this institution, the total cost of the stereotactic procedure including all professional fees was an average of $2,000 cheaper than excisional biopsy. Even including the costs of all those with benign and malignant lesions who had a stereotactic biopsy followed by excisional biopsy, the average cost of each biopsy was reduced by more than $1,600 over what it would have been if surgical biopsy alone had been done in all cases.[9]

Dr. Parker also points out that large core needles are helpful in making a definitive benign diagnosis, whereas fine needle aspirations are less capable of doing this.[23] If a definite benign diagnosis can be made, there will be



Figure 1A. Routine mediolateral oblique mammographic image.



Figure 1B. Routine craniocaudad mammographic image.



Figure 1C. Stereotactic initial scout view of the lesion.

Figure 1. The steps taken in performing a stereotactic biopsy on a stellate lesion in the superomedial aspect of the right breast. Multiple core biopsies were obtained, all of which showed an infiltrating carcinoma with a tubuloductal pattern. A right segmental mastectomy and axillary dissection was done about two weeks later and an infiltrating tubular carcinoma was reported measuring 10 x 7 x 8 mm in size which corresponded to the radiographic lesion. However, an incidental 2-3 mm hard nodule was seen by the surgeon at the inferior aspect of the surgical defect. This was found to be a second primary carcinoma. The latter was an infiltrating duct carcinoma that was cytoarchitecturally different from the larger lesion. The lymph nodes were negative for metastatic malignancy.

less doubt of a false negative diagnosis. He states that fine needle aspiration of the breast is only satisfactory if the cytopathologists are "top-notch," whereas expertise in evaluation of core biopsies is widely available. A similar view was expressed in several other papers.[26,62,63] Dowlatshahi[26] felt that FNA was generally preferred over core biopsy but others[64] have criticized both his methodology and conclusions.

Dr. Page feels that FNA of the breast is best "for diagnosing cancer, whereas core biopsy may be better for benign disease. Since it can give a specific diagnosis˘ core needle biopsy can give specimens that in many ways are better than what you would get with an open biopsy."[23] Dr. Page says the biopsies are much better with current spring loaded biopsy guns than with handheld units. The needles penetrate tough fibroadenomas, and post procedure hematomas are a less frequent problem now. Even when a calcified artery was inadvertently punctured during FNA, the resultant hematoma did not require intervention. Core biopsies may be preferred for deep lesions.

It should be noted that the older versions of some of the biopsy guns do not have a powerful enough spring to always get satisfactory biopsies of tough lesions, such as fibroadenomas. I understand that this has been corrected in the newer models.

The material obtained from either a fine needle or core biopsy can be used to evaluate the hormone receptor status and other prognostic factors.[9,65]

Fourteen-gauge core biopsy is much more likely to be able to distinguish between carcinoma in situ and invasive carcinoma.[63] However, sampling errors can result in mistakes in this differentiation with core biopsy also.

In my opinion, repeat FNA or core biopsy or open biopsy should be recommended for virtually all lesions that have inadequate material for diagnosis[62] or exhibit atypia. Open biopsy or repeat FNA or core biopsy is also

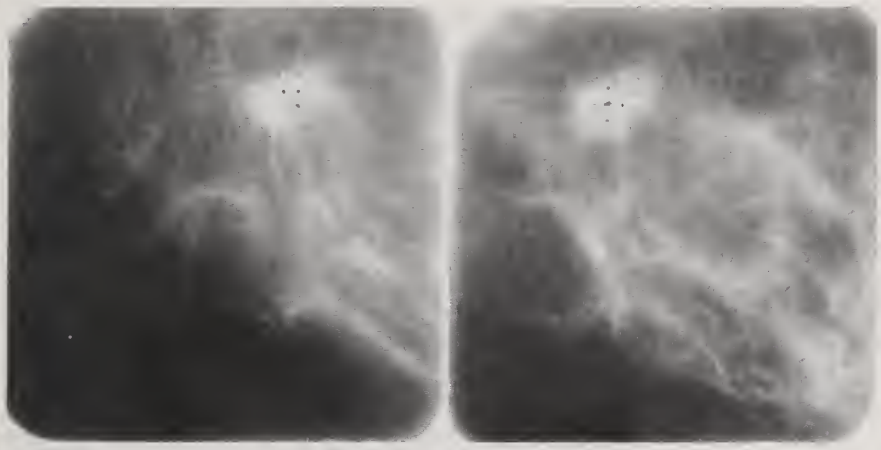


Figure 1D. Stereotactic scout views with target areas marked.

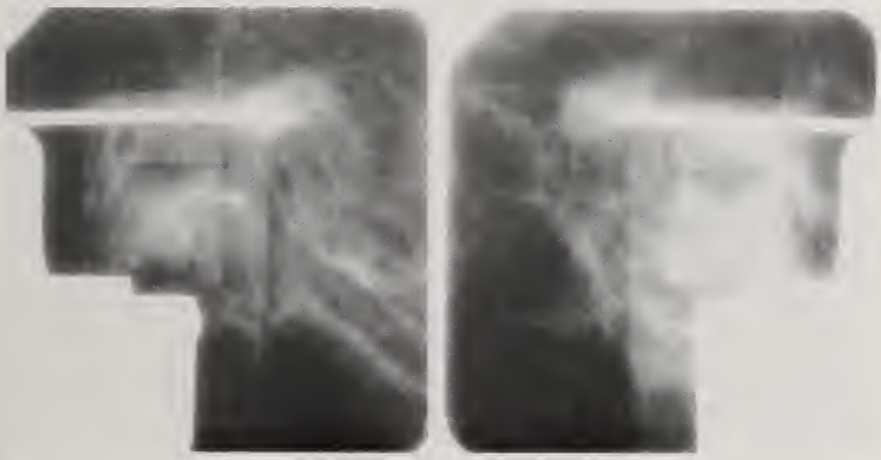


Figure 1E. Stereotactic views showing the biopsy needle before firing.

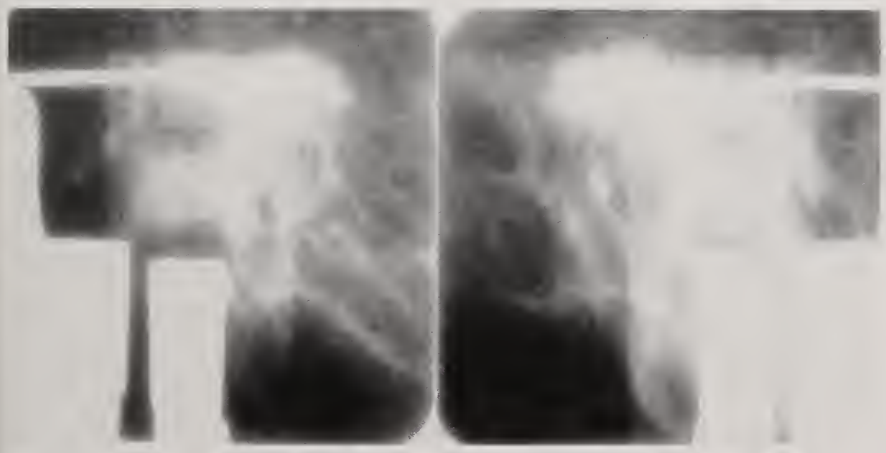


Figure 1F. Stereotactic views showing the biopsy needle after the biopsy.

suggested if there is a very strong clinical or mammographic suspicion of malignancy, and no definitive benign diagnosis was made with FNA or core biopsy. This points out the need for close cooperation between the surgeon, pathologist, radiologist, and patient.

Needle Tract Seeding

The next issue is whether percutaneous biopsy might cause needle tract seeding. In a review of 11,000 FNAs done on lesions in various parts of the body, there were only two clinical cases of needle tract seeding, both for carcinoma of the pancreas. In one of those cases, a total of 10 passes were made with the needle.[66]

In response to a questionnaire to institutions doing about 63,000 FNAs in the past 4 years, there were only three reported cases of viable neoplastic cells along the needle tract, and one of those cases was one of the previously referred to pancreatic carcinoma cases. The other cases were carcinoma of the cervix and renal carcinoma.[67]

In a study of 1,576 cases, there was no difference in 5-year survival without clinical evidence of disease whether or not FNA was done.[68]

In a study of over 3,000 FNA biopsies of the breast, there was no evidence of malignant seeding along the needle tract.[21] In a study of several hundred patients with breast cancer, in which the diagnosis was made by FNA, and a similar sized group of patients in which the diagnosis was made by excisional biopsy, there was the same mortality in a 10-year follow-up.[69] A 15-year follow-up of 370 patients who had surgery for breast carcinoma after FNA compared to a group operated on without FNA showed the same survival.[70] Therefore, there is no known risk of spreading viable tumor from FNA of the breast.

However, Harter et al.,[71] noted that since 14-gauge Tru-cut needle biopsy of the prostate has a 1% chance of seeding along the track, it is possible that a similar rate could occur with a 14-gauge core biopsy of the breast. They report one case in which FNA of the breast performed by a primary physician was benign, but because of the suspicious nature of the lesion, 14-gauge core biopsy was performed stereotactically. This showed malignancy. However, at wide local excision, seeding along the tract was detected. Harter feels if mastectomy is to be done, seeding along the tract is "probably irrelevant," but if more minor surgery is done, excision of the needle tract "should be considered." At several medical centers during subsequent surgery, most surgeons chose to excise the needle tract if mastectomy is not done, if FNA or core biopsy demonstrates malignancy.[9,15]

Hall[5] found that the positive predictive value of a suspicious lesion seen on mammography, that was nonpalpable, was 30%. However, if the suspicion on mammography was minimal, then the probability that cancer would be found was only 4.7%. He felt that following minimally suspicious lesions mammographically rather than recommending biopsy would probably not change the prognosis for these patients and would avoid many operations. If the minimally suspicious lesions are eliminated, the positive predictive value of the mammogram at his institution becomes 41%. These results are better than at many institutions. Hopefully the use of stereotactic units can decrease the proportion of negative open biopsies even more.

Although there is a learning curve with all new procedures, it is important that the team of the technologist and radiologist have observed these procedures being done on patients and have done multiple practice runs on a phantom. A phantom may be constructed out of readily available materials. A raisin is slit and some granules of a crumpled calcium tablet are placed inside it. The raisin is squeezed shut. Then a slit is made in a suitable object such as a squash. The raisin is placed within the squash and the squash's edges are squeezed closed. The calcifications are seen on X-ray and the lesion is localized, including verification of the needle tip. Then aspiration core biopsy is done. The core is then inspected, the presence of the raisin color in the squash core confirms the biopsy was correctly done.

Finally, the first patients biopsied at an institution should be done with an experienced user in attendance. Drs. Fajardo and Parker do not feel that large numbers of stereotactic biopsies need to be done for an operator to be skilled in this technique.[11,18]

An increasing percentage of breast biopsies are now done under ultrasound guidance, due in part to better equipment and in part to greater experience.[9,18] Malignancies are usually hypoechoic. Dedicated equipment is not needed, and axillary lesions can be biopsied.[72] There may also be a role for ultrasound guided biopsy for some palpable masses. If a tumor is far smaller than the desmoplastic changes around it, unguided FNA may result in a lack of sampling the malignant cells. Ultrasound guidance should make this type of false negative most unusual.[72] For palpable lesions, the mass should be fixed between two fingers and the tissue above compressed by the transducer. Ultrasound guided biopsies of small or deep masses can be difficult. Practice with a gelatin mold with fruit suspended in it is useful.[18] FNA of the breast under ultrasound guidance had a sensitivity of 92% and specificity of 93% in a 1987 study.[28] However, not all lesions can be seen under ultrasound. Masses smaller than 6 mm and microcalcifications without an associated mass are examples.[72] Also, seeing the needle tip can be a big problem with some equipment even with a 7.5 MHz transducer. Recently one manufacturer of ultrasound equipment has introduced a fine-needle whose stylet tip has a filament that results in a clear signal on the location of the needle tip.

Suggested Protocol for Biopsy

It is clear that stereotactic biopsies are an advance in caring for patients with most suspicious, nonpalpable lesions of the breast. There is no uniformity of advice on an optimal work-up of these patients, but it is proposed to start as follows:

1. All patients must be referred to us by the patient's physician.
2. The radiologist will review the case and determine if the area should undergo biopsy by stereotaxis or ultrasound.
3. If a malignancy is found, definitive treatment will be recommended.
4. If a definitive benign diagnosis such as fibroadenoma is made by FNA or core biopsy, then no further work-up should be required. The FNA results may be a little less reliable. However, until there is more confidence in the results, follow-up mammograms will be done at six months whether FNA or core biopsy was used. A system will be set up so that reminders for these appointments will be sent out at the appropriate intervals. Thereafter, mammograms are suggested at 12, 24, and 36 months.
5. If no malignant cells are found, but no specific benign diagnosis is made, what we recommend next will largely be determined by the mammogram. If the mammogram shows a very strong suspicion of malignancy, rebiopsy in radiology or referral for open biop-

sy is suggested. If the mammogram shows a low suspicion of malignancy, then a follow-up of the affected breast is recommended at 6, 12, 24, and 36 months. Clinical factors may modify these recommendations.

Conclusion

A stereotactic breast unit can be used to localize lesions, or to guide fine needle or core biopsies of nonpalpable suspicious areas. It is cheaper than a surgical biopsy, has less morbidity, and does not scar or deform the breast. Its accuracy is high, but it is not infallible. If a complex cyst is suspected, a fine needle is suggested to start. Core biopsies are preferred to make definitive benign diagnoses in solid lesions such as fibroadenomas, and the immediate sequelae are no more serious than that seen with FNA. Although the unit should decrease the proportion of incisional biopsies done for suspicious mammograms somewhat, it will not totally replace this type of surgery. It should decrease the percent of open biopsies done for diagnosis before definitive therapy. It should especially decrease the proportion of open biopsies done for lesions with a low probability of malignancy. It should decrease the time to diagnosis in some cases when the dilemma is whether the lesion justifies biopsy or follow-up. Finally, it should decrease the cost and morbidity. This article has summarized some of the advantages and disadvantages of the stereotactic unit, and hopefully this discussion will be helpful to surgeons and their patients with a suspicious breast lesion.

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Medical Student Abuse: A Review of the Literature and Experience on One Campus

Glenn H. Lytle, MD; June E. Holmes, EdD; Milton C. Olsen, PhD

Medical students, when questioned, report a fairly significant rate of abuse during their education. A review of the literature shows the reported frequency of such abuse, as well as the several forms it may take. A review of one campus's experience shows a similar prevalence, as well as the effect of educational seminars on the perception of such abuse.

ALTHOUGH THE TOPIC OF MEDICAL STUDENT ABUSE has not been studied extensively, the few scattered reports on the subject have received disproportionately widespread coverage by the media. The purpose of this presentation is to review some of the literature and to report on a study of abuse completed at the University of Oklahoma College of Medicine-Tulsa (OUCMT).

There are times during medical school training when students may feel uncomfortable as they are exposed to different academic and clinical situations and have new experiences. Although students may feel uneasy during those times, they may not necessarily feel abused. Principles of education in general, and principles specifically developed for the "adult learner," have established the climate necessary for ideal learning. Most feel that this climate should be *"safe, caring, accepting, trusting, respectful, and understanding."*[1] Anxiety levels should be appropriately controlled—high enough to motivate, but not so high as to block learning.

The literature dealing with the subject of abuse is limited, but there has been some scholarly interest. One of the early spokespersons on this subject was Dr. Henry Silver, a pediatrician, who wrote on this subject while at the University of Colorado School of Medicine. In 1982 he wrote about the transformation that took place in medical students over time. He described the incoming first-year medical students as "eager, alert, enthusiastic, and excited men and women from various walks of life, and a variety of educational backgrounds...."[2] He went on to report that "...he was saddened when he thought of the gradual transformation that would take place in them over the next several months; many would become cynical, some dejected, others frightened or depressed, and a few filled with frustration. The joy, the 'eager beaver' anticipation they now had, might never return."[2]

Having been trained as a pediatrician, Dr. Silver found it quite natural to equate this change with the changes he had seen occur in abused children. Over the past decade, until his death in 1991, Dr. Silver continued to do research and write about the issue of medical student abuse.

In 1984 Silver and Rosenberg reported the results of some inquiries they had conducted concerning the subject of abuse.[3] In this project, they sought comments from three groups: (1) medical students enrolled at the University of Colorado School of Medicine, (2) physicians who had voluntarily responded to Dr. Silver's previous article on the subject, and (3) associate and assistant deans of medical schools who were involved with student affairs. One medical student was quoted: "I went through nights of a lot of self-doubt and low morale and

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losing a lot of my motivation. It affected my self-confidence quite a bit."[3]

Comments from two physicians included: "I can still hear the laughs of the arrogant professor putting me down. I wonder if he remembers?" and "I feel that it hurt my attitude and made me a worse doctor, certainly a more nervous, less self-assured one. During school, the abuse grossly interfered with our ability to learn."[3]

A different type of response is seen from the comments of deans of medical schools. Their answers to the questions about abuse included these samples: "We here agree that the medical educational system is stressful, but whether or not the clinical term 'abusive' can be applied is questionable. There has never been any evidence of abuse at our school."[3]

In response to articles about such abuse, an essay by Dr. Robert Petersdorf, president of the Association of American Medical Colleges, published in *Academic Medicine* stated:

"Last year a pair of articles published in *JAMA* received extensive coverage in the lay press. The papers dealt with student abuse, a term quickly picked up on with unholy glee by the media. Not only did medical schools have trouble attracting students, the press reported, but once they got them, they abused them.

"*Abuse* is an emotionally charged word, conjuring up images of defenseless victims unable to control their destinies or to escape their tormentors. It is a word, I believe, that is too strong to describe what happens in our medical schools and teaching hospitals. It is a word that does not accurately reflect the totality of medical students' educational experience."[4]

Petersdorf was specifically referring to two articles which were printed in *JAMA* in January 1990. These articles by two different groups of researchers reported on separate surveys conducted to assess the incidence, severity, and significance of medical student abuse.[5,6] One of these articles was by Silver and associates.[5] The questionnaire used has become a standard in the field. In Silver's paper, it was reported that 46% of all students stated they had been abused, including 81% of seniors. The paper went on to state that some 50% of those abused said that the episode of abuse affected them adversely for one month or more, and 16% stated it would always affect them.[5] The Association of American Medical Colleges (AAMC) has also addressed the topic of student abuse with some of the questions utilized in their annual graduating student survey. In the past two surveys, approximately 40% of respondents felt they had been publicly belittled or humiliated, with a much smaller percentage having felt threatened or physically abused.[7,8] Based on these studies, an investigation of possible abuse was carried out at the University of Oklahoma College of Medicine–Tulsa (OUCMT).

Materials and Methods

The principal research tool used was the survey form as developed by the late Dr. Silver and his associates. Third- and fourth-year students were first given this questionnaire without any significant introduction or discussion of the topic of abuse. The responses were kept anonymous, with the forms being identified only by class year and sex of the student. Several months later, these same students attended a mandatory conference on the sub-

Table 1. Comparison of Perception of Abuse Before and After the Seminar on Abuse for Third-Year Students

Categories	Pre-Seminar	Post-Seminar
Shouting		
Pre-Clinical Faculty	21%	37%
Clinical Faculty	36%	52%
House Staff	37%	53%
Humiliation		
Pre-Clinical Faculty	42%	53%
Clinical Faculty	58%	68%
House Staff	58%	68%
Physical Abuse		
Pre-Clinical Faculty	5%	0%
Clinical Faculty	5%	5%
House Staff	11%	5%
Sexual Harassment		
Pre-Clinical Faculty	42%	36%
Clinical Faculty	58%	58%
House Staff	53%	53%

Table 2. Comparison of Perception of Abuse Before and After the Seminar on Abuse for Fourth-Year Students

Categories	Pre-Seminar	Post-Seminar
Shouting		
Pre-Clinical Faculty	32%	28%
Clinical Faculty	39%	61%
House Staff	33%	61%
Humiliation		
Pre-Clinical Faculty	33%	44%
Clinical Faculty	83%	78%
House Staff	55%	66%
Physical Abuse		
Pre-Clinical Faculty	11%	0%
Clinical Faculty	6%	0%
House Staff	6%	0%
Sexual Harassment		
Pre-Clinical Faculty	22%	39%
Clinical Faculty	39%	50%
House Staff	33%	45%

Table 3. Summary of Abuse on the Tulsa Campus — All Students		
Categories	**Agree**	**Disagree**
Abuse by Attendings	71%	29%
Abuse by House Staff	87%	13%

ject of medical student abuse. During this seminar, some of the pertinent literature and major issues were discussed. In addition, some examples of potential abuse were discussed after viewing videotapes of interactions between students, residents, and clinicians. Following the seminar, students responded to selected items from the original questionnaire.

Surveys were completed by nineteen (19) third-year students both before and after the seminar. Eighteen (18) fourth-year students completed the preliminary survey, but only twelve (12) completed the survey after the seminar. Comparisons of pre- and post-seminar results are presented in Tables 1 and 2.

Following the seminar, students were asked if abuse occurred on the OUCMT campus. These results are shown in Table 3.

Results

The medical students perceived that they are subjected to abuse during their clinical years on the Tulsa campus. The percentage of students recognizing this abuse is significant, and about equally attributed to both faculty and residents. The seminar on abuse had mixed results. It appeared to heighten the recognition of the non-physical forms of abuse, such as shouting and humiliation. By the same measure, it seemed to clarify what could be termed physical abuse, and served to lessen the perception of the occurrence of that form of abuse. For sexual harassment, the general trend appeared to be towards a heightened awareness after the seminar.

Conclusion

Medical students feel they are abused during the clinical years, although this abuse rarely takes the form of physical abuse. Seminars on the subject tend to heighten awareness and clarify issues about such abuse. Because this problem is apparently so prevalent, it is important that medical school faculty continue to present educational programs directed toward students, housestaff, faculty, and attending physicians. In addition, mechanisms need to be established for reporting and correcting abuse. These procedures should be developed through close cooperation of student government, faculty boards, and the dean's office.

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BERTHA M. LEVY, M.D.
PEDIATRIC CLINIC

Leaders in Medicine:
Bertha M. Levy, MD

She realized that when Medicaid and Medicare were enacted by Congress in 1965, practicing medicine would never be as unfettered as it had been. But she believed she was free to continue giving the best care she could to all her patients...

Story by Richard Green
Photos by Robert Taylor

WHEN THE GOLDEN AGE OF Medicine ended on January 1, 1966, as some physicians aver, Dr. Bertha Levy spent the next morning beginning to implement Oklahoma's new Medicaid plan. Oklahoma was one of only six states to have its plan approved by the Social Security Administration for the January 1 start date, and Levy had been the state's representative at a White House signing ceremony.

In the receiving line, President Lyndon Johnson had beamed down on her, enveloping her hand in both of his, and told her how much he had admired the late Oklahoma Senator Robert S. Kerr.

Implementing the new state plan meant that she was, in effect, in charge of leading Oklahoma's doctors out of the Golden Age. No consensus for a label has emerged for this more modern era, but there have been many variations associated with Government Intervention.

Levy's career as a pediatrician had spanned the Golden Age—from the advent of antibiotics—and she had enjoyed practicing medicine as thoroughly as any physician. She also realized that when Medicaid and Medicare were enacted by Congress in 1965, practicing medicine would never be as unfettered as it had been.

But she believed she was free to continue giving the best care she could to all her patients. And that, says her cousin Harriette Orbach, was probably why she went into medicine in the first place. "It does something for her to do something for others."

So it never dawned on her during most of 1965 that the new legislation would mean any more to her than any other physician, much less that she was about to become one the earliest pioneers of the new publicly funded health insurance programs. But Lloyd Rader, director of the state Welfare Department since 1951, had a way of getting his way. And he thought that the unsuspecting Bertha Levy would be an ideal person to get the programs off and running.

Rader never told anyone why he had selected Levy. She remembers him saying he needed her in what would be a most challenging job. And even his detractors would admit that Lloyd Rader was a shrewd judge of character.

* * *

WITHOUT HESITATION, BERTHA Levy says that her parents had the biggest influence on her character. While that admission doesn't seem particularly revealing, it is about as open or insightful as she gets about her private life. Part of the reason is that she considers her private life private. Her definition of *private* also is very broad, extending to virtually all her non-public relationships. Adversities? Regrets? Yes, she's had some professionally and personally. End of subject.

Her cousin Harriette smiles and says, "If you want to ask Bertha

for examples of unhappiness in her life, or why she never got married, you'd better wear a suit of armor."

Another reason she is taciturn about her private life is that she isn't very introspective. She has no idea, NONE!, why she chose to become a doctor. She isn't sure why she joined the Navy during World War II. But, she adds, it was probably patriotism. Other than to note that she was one of only two women in her medical school class of 120, Levy says she didn't give it another thought.

She says maybe she was too dumb to know that she should have been focusing on those things.

Instead, she concentrated her energy on mastering the task at hand. She left Baton Rouge after two years at Louisiana State University basically the way she'd gone in: relatively mature and self-confident. But more importantly, she'd made straight A's and been accepted to medical school at Tulane. That was the general idea. Did anyone tell her that a woman, a Jewish woman, in that day and age, might not get admitted? "If they did, I didn't hear it. And it wouldn't have made any difference anyway. My parents thought becoming a doctor was a wonderful idea, and they were completely supportive. That's all I needed."

* * *

TWO AND THREE GENERATIONS before she was born, Bertha Levy's ancestors left eastern Europe for the "land of opportunity" and wound up in Baton Rouge parish in Louisiana. She has a Tiffany watch that belonged to her mother's grandma.

She also has a story about her father's mother. "He settled in Louisiana first and then sent for his wife and two children. They left Poland, landed in Boston, and without knowing any English, she managed to find him in Grand Coteau, Louisiana. Think of it!"



The Victor Levy family in 1928. Clockwise from left: Bertha, Aaron, Coralie, Annie, Victor N., and Victor.

They had five more children, including Bertha's father, Victor Levy, and then set out for Oklahoma Territory sometime between the '89 Land Run and statehood.

Victor and Coralie Levy had four children between 1912 and 1924. The siblings are all still alive and quite close despite being far flung—two in Florida, one in Maine, and one in Oklahoma. Bertha came second, in 1914, in the family's home on Northwest 16th between Walker and Dewey. When she was 4, the family moved to a house at 717 Northwest 22nd, where they lived for the next 30 years. (Only a couple of years ago, as Bertha was driving by for a look, she was shocked to find the house gone. It apparently had been moved; she had no interest in finding out where.)



Lt. Levy was one of the U.S. Navy's 41 female physicians during World War II.

Bertha's childhood was happy and secure. Her parents had an ideal marriage, and their

neighborhood was loaded with kids. On bad weather days, Mrs. Levy would open the doors to some adjoining rooms and convert the downstairs into a hardwood-floor racetrack for her children and their friends on tricycles and roller skates. It was, after all, the "Roaring Twenties." She also occasionally got a quarter on Sunday afternoons that paid for the streetcar, popcorn, and entertainment at the downtown Orpheum Theater, including vaudeville acts, cartoons, a newsreel and a couple of shorts and a feature movie.

Other times, Bertha recalls lying under a tree on a piece of tapestry she called "the green thing," talking with friends, maybe drinking a Nehi, and looking at the passing clouds.

She liked school and reading but never considered herself bookish. She attended Wilson elementary school, which is still open, but remembers when their water came from a well. In 1969, at the school's 50th anniversary party, she was selected as one of the school's four outstanding alums from 1919 to 1925. Another selected was E.L. Gaylord, who became owner and publisher of *The Daily Oklahoman.*

Although Victor Levy had passed the bar exam, he didn't practice very long. "He had too much integrity to do some of the things that he thought lawyers had to do, so he quit," Bertha says. She remembers that he went into the furniture business with his brothers and did very well. The family employed a maid for a few years until October 1929, when the stock market crashed. "My father lost everything," Levy says.

So did thousands of other Oklahomans, and some never recovered either financially or emotionally. But Victor and Coralie Levy were extraordinarily stable people. He went into the insurance business because he didn't need capital to do so and probably because he saw firsthand the value of insurance.

He never liked the business and was only marginally successful, yet he only rarely complained and never at length, according to Bertha.

"My mother was very strong," Bertha says. "We were poor in the thirties, but she never thought poor or talked poor, so we didn't get the impression that we were."

Despite the tough times and the stress, "I never heard my parents quarrel. Not once."

Stability amid the chaos and desperation shielded her from the reality of human want and misery that she would witness later in her training at Charity Hospital in New Orleans. And a stable home also was a launching pad for her success. It imbued her with self-confidence, although she knew next to nothing about doctoring.

She and her siblings were treated by a pediatrician, Dr. Salomon, who lived across the street. She has two strong childhood memories of him. "One is of him in my bedroom, in the evening, wearing a tuxedo and reassuring my mother that my earache would go away. In the other, I am a teenager about to have my appendix removed and just before I go under, he comes into the room, as I had requested, to hold my hand."

* * *

As a practicing physician and putative role model, everyone around her knew where she stood. "Apply the Golden Rule; it's that simple."

BERTHA LEVY GRADUATED FROM Central High School in 1932 and won a scholarship to LSU. That, plus living with her grandmother in Baton Rouge and being frugal (but not miserly), enabled Bertha to get by financially. She satisfied all the medical prerequisites in two years and from that rather narrow perspective enrolled at one of the best medical schools in the country, Tulane.

Although she obtained an excellent medical education in some respects, much of what she learned was about to become antiquated... fortunately.

Acute and chronic infectious diseases were treated symptomatically, and the physician played only a minor role in the course of many illnesses. She didn't see the miraculous effects of sulfa drugs on bacterial diseases until she was an intern. "This 5-year-old girl was gravely ill with pneumococcal meningitis. Someone went to great lengths to get a sulfonamide to use on her, and she completely recovered. It was like a miracle, thrilling. There was so much excitement that the head of the lab himself came in to do the spinal."

Her medical education also indirectly taught her more about

race in America. Levy says she was raised to believe that people are created equal. During her clinical years in New Orleans, it was evident that the white hospital staff didn't treat people equally. "The doctors called elderly black people by their first names but never addressed an elderly white person that way."

At the time, Levy didn't call this behavior racism; she probably wasn't even conscious that it was wrong, except if she were to join in. She was capable of recognizing the way things were, but unwilling or unable to alter her own conduct.

In later years, she realized that calling an old black gentleman Freddie wasn't just racism, but part of a general pattern of behavior. "It wasn't any worse than the way some doctors treated their white welfare patients," she says.

In other words, respect and courtesy were extended or withheld according to factors such as one's race, economic status, and educational level. By that time, as a practicing physician and putative role model, everyone around her knew where she stood. "Apply the Golden Rule; it's that simple."

* * *

AT THE SUGGESTION OF Tulane's medical school dean, Dr. Levy applied and was accepted for the internship program at Women's Hospital in Philadelphia. Either she had no personal considerations or they were secondary; she would have applied virtually anywhere Dr. Bass recommended.

Like perhaps most doctors of her era, Levy says she profited enormously from the rotating internship and bemoans its passing. She acquired a broader background and perspective on problem-solving, but the academic year 1938-39 had no influence on her future plans. "I always wanted to be a pediatrician. I don't know why, but Dr. Salomon may have had something to do with it; his patients adored him."

Levy spent 15 months in a pediatrics residency at Bradford Memorial Hospital in Dallas. A few memories stand out:

...Pediatrician Gladys Fashena, who taught her how to think critically. "Before I met her, I was so naive and self-assured it was a wonder I learned anything."

...A trial of a sulfa drug, during which blood was drawn at set intervals and, though everything was standardized and the blood levels of the drug should have been the same, they were always different, sometimes widely so.

...An infant admitted with an enlarged spleen and a very abnormal blood count. Renowned hematologist Joe Hill thought the baby had leukemia, which was then invariably fatal. The baby didn't seem to get very ill, however, and gradually and inexplicably, the baby recovered.

In the summer of 1941, as the wars in Europe and the South Pacific intensified, Levy learned that Dr. Salomon's assistant was going into the service. He needed a replacement and Levy, wanting to come home and begin practicing, was an excellent choice. He had known her practically all her life, and she wasn't going to be drafted. (She completed her pediatric residency at Cincinnati's Children's Hospital in the early 1950s.)

They practiced together for about 18 months, and Levy came to the happy conclusion that Salomon was every bit as good a doctor as she had thought. She admired his communication skills, especially the way he listened to his patients and their parents. They parted company when another pediatrician who was about to join the service asked her and Salomon if she could take his practice. They agreed, and she was on her own in 1943.

"I learned rather quickly that confining a kid to bed has no effect on the course or the outcome of most childhood illnesses. So why make everyone more miserable?"

However, less than two years later, in March 1945, she joined the Navy. Perhaps her motive was patriotism, or thinking that the war might end without her. Did she think about where she might be assigned? No. Her contribution to the war, she says ruefully, was "fighting the battle of the family medicine clinic" at the naval base in Corpus Christi, Texas.

As one of the Navy's 41 female physicians during World War II, Levy spent about a year as the



At the Variety Health Center pediatric clinic in Oklahoma City, Dr. Levy and Darlene Johnson, pediatric nurse practitioner, visit with 10-month old Angela and her mother, Maura Leiva.

clinic's pediatrician. Though the practice was uneventful, she was happy enough with it. She has a picture from then of herself and a few nurses posing beside a roadster on their way to a picnic. They are all holding aloft big clunky bottles of beer. Levy maintains hers was a prop—she was the designated driver.

The one drawback to her service was that she obviously had the lowest rank, lieutenant j.g., of any of the clinic's physicians. Even the interns had higher ranks.

She didn't officially complain about this discrimination during her hitch, but later protested it by resigning from the Navy completely rather than signing on with the reserves. But as she says, "If I had joined, I might have been activated for Korea like many of the younger male physicians who had been in World War II."

Many of them bitterly resented having to leave their practices. And when they returned, Levy saw that some of their attitudes remuneration had changed. "It was like, 'I'm gonna get mine now.' "

She could understand their frustration, and even sympathize to an extent, but she had little patience with those who complained too much or too loudly. She recalls one evening when the county medical society hosted some foreign visitors, and one doctor who had had too much to drink "bitched" at length to the guests about how this doctor, a reservist for many years, was too old to be called up to go to Korea. To Levy this was an *unforgivable* breech of etiquette.

* * *

PRACTICING AFTER THE SECOND great war combined the considerable advantages of being able to use the new antibiotics, immunizations, and enhanced x-ray capabilities with still minimal

intrusions for paperwork and other regulatory demands.

This was the Golden Age because physicians were not only still kindly and available, they were also enormously more effective. To the doctors, particularly, and to patients whose lives bridged the pre-antibiotic and the antibiotic eras, there is no underestimating the profound effect that this progress represented.

In the span of a few years, doctors who had been unable to affect the course of diseases were now curing them routinely. Once-common diseases such as diphtheria were vanishing. Levy saw her last case before 1950.

Other diseases, such as childhood leukemias, remained impervious to treatment. And although she couldn't help these children, one of them inadvertently helped her. A nurse told Levy that before the 10-year-old had died, he had said, "I know something is bad wrong with me, but nobody will tell me what it is."

Levy says she never again withheld pertinent information from a patient who wanted to know it, although she was careful not to extinguish hope. "The world lives on hope. How else would so many people who live in such desperate circumstances survive?"

(When Levy refers to her patients, she often means their parents and/or guardians, but she leaves it up to the other person to figure this out.)

"I always listened to my patients," she says, "because I enjoyed the conversation and learned from them. But it took awhile for me to realize that I should stop telling parents what to do and just give them a framework. I used to tell parents to keep a child with a fever in bed.



Dr. Levy adjusts one of the many paintings which cover the walls in her home. Over the years most of them hung in her various offices and were enjoyed by her patients.

But I learned rather quickly that confining a kid to bed has no effect on the course or the outcome of most childhood illnesses. So why make everyone more miserable?"

It also took awhile to discover the secret of getting recalcitrant youngsters to eat. "Nothing. They can eat when and what everyone else eats. Some mothers try everything to get the child to eat and of course he loves the attention. If I had one rule of thumb it was never tell your patients to do something that you wouldn't do yourself."

During the 1950s, Levy still made lots of house calls. "I used to just pick up and go when I was called, never giving a thought to safety. Of course, it was a different world then. But even so, some doctors already considered house calls a waste of time. I had a different view. I know I learned a lot more about a patient from one relatively brief home visit than from several office visits. Often, that saved time."

Levy was not critical of other physicians' professional judgment, but their professional conduct was

something else. For example, one doctor who told an agitated parent that he would be right over to see her ill daughter stopped to play a round of golf first. Since the child's fever was already high and ear pain was severe, the increasingly anxious parent called Levy, who came immediately. When Levy learned that the doctor had played golf before making the home visit, she was furious and, according to the mother, "really let him have it. To him, a couple of hours weren't going to make any difference," says the parent. "But Bertha didn't see it that way. When you're called, you respond. Medicine was her whole life. She didn't have time for anything else. Period."

* * *

THINGS CHANGED IN 1965. IN A move that probably surprised her friends and colleagues and even her to an extent, Dr. Levy went to work for Lloyd Rader, the director of the state Welfare Department and probably the most powerful person in Oklahoma government over most of his 30-plus years in that position.

The job was administering the Medicaid program, which began in Oklahoma in 1966. She worked several hours a week and kept her private pediatric practice. The next year, Levy also began administering the Medicare program for elderly and disabled Medicaid recipients and, though the workload dramatically increased, she added the layers of staff necessary to process the daily blizzard of claims.

Characteristically, Levy doesn't say much about why Rader chose her or why she took the part-time job. "I never asked him and he didn't say." But, according to Rader's long-time aide George Miller, Mr. Rader probably knew that Levy took care of the children of many doctors in town. And he wanted the new program to be run not by a layperson, as in most states, but by a practicing physician. This was a shrewd move, as Levy was able to get the programs off to a smooth start, keeping claims moving and doctors relatively satisfied.

Rader also knew that Levy had been treating the children of indigent people for years in a free clinic sponsored by an organization called the Variety Club. This would have been important to Rader because he wanted someone who was sympathetic to the department's constituents. By 1965, after more than 20 years of providing professional services weekly at the Variety Health Center, she knew that the popular image of the Welfare Queen was a myth.

Certainly some incorrigibles and con artists showed up, but the vast majority were decent, uneducated poor people of all races who lacked the wherewithal to escape from what came to be known as "the other America," after the name of Michael Harrington's best-selling book of the time.

Levy says Mr. Rader's offer came at a fortuitous time because she needed the extra money. She also points out that not many 51-year-old people have the opportunity to begin a new career, at the top.

Levy had to satisfy multiple constituencies, the federal government, physicians, health providers, patients, and of course, Lloyd Rader. In time, the balancing act required more delicacy—as the programs expanded enormously (due to demand and the department's dedicated sales tax revenue) and ballooned with regulations and requirements.

"If I had one rule of thumb it was never tell your patients to do something that you wouldn't do yourself."

That's not to say that Bertha Levy compromised her values or integrity. She says Mr. Rader never questioned her medical judgment. Some physicians did, but these mainly involved honest differences of opinion. A large part of her job involved fielding questions and complaints from Oklahoma's physicians. One early recognition that saved her a lot of grief was never to defend the indefensible.

Despite her lack of management experience, Levy was an exemplary supervisor in an office that grew enormously in volume of work and number and layers of employees. Her initial three employees swelled to more than 250. Yet, she was "respected and loved by most of us on her staff," says Barbara Whittlesey, who came aboard in 1967. This was because Bertha was "fair and

showed that she cared about us. She played multiple roles in that office: mother, sister, friend, confidant, advisor. She also seemed to be able to recognize everyone's potential and then help them achieve it, if need be."

Simultaneously, the work got done, people were motivated, and as a result, Whittlesey says, employee turnover was very low. Although she was always there for her staff, Levy apparently wouldn't burden any of them when she needed support. In February 1979, she got a phone call late one night to come and identify the body of a woman who was believed to be her niece. She had been struck by a car.

It could not be. Kathryn had just spent part of the Christmas holidays with Aunt Bertha. Although Kathryn, who was 29, had endured some unhappiness, that was behind her, and the two had had a wonderful holiday. A new intimacy had developed between them; they were like mother and daughter.

"I can remember yet... she had the look of faint surprise on her face. And it struck me for the first time how much she looked like my mother."

Tears well up in Levy's eyes. She fights them back and says she isn't over her niece's death yet because she never got it all talked out. When she needed to talk, no one wanted to hear her. At least, not to the extent she needed. This may be so. But it is also true that many people who suffer such a shocking, senseless loss never recover fully. The passing years may not yield new perspective nor dilute the heartache. Barbara Whittlesey says Bertha was sad for a long time afterward.

* * *

SOME SAY EVENTS DON'T conspire, only people do. But sometimes, it sure seems like events are in the saddle. It appeared that way when Dr. Levy became Mr. Rader's top medical advisor in 1965, and it looked that way again in the early 1980s when it was time for her to resign.

Her career at DHS was closely linked to his. Theirs was a relationship based on mutual respect and support. He depended upon her, among many other things, to keep the physicians informed and satisfied and not to do anything to embarrass the department. She counted on having access to him and his backing when she needed it. Once, she had written an impolitic letter to a U.S. Senator and he had called Mr. Rader angrily asking, "Who the hell is this?" She says Rader just laughed about it, but the lesson was learned and the mistake not repeated.

Another time, Mr. Rader had given one of her subordinates a raise but no one else. When Levy found out about it through the office grapevine, she told Mr. Rader that if he ever did anything like that again without speaking to her first, she would quit. If he did, she never heard about it.

When the politicians said it was time for Mr. Rader to go, the bureaucrats, currying favor of those who wanted to unearmark the department's dedicated sales tax money, were happy to see "the Rader crowd," including Bertha Levy, go as well.

She was not happy, and her staff was angry that the person they revered had been ensconced in an office with little or nothing to do. Her retirement party in January 1984 was actually her second, both chronologically and in size.

Three years earlier, she had given up her pediatric practice. Although she says the immense amount of reading she was doing, keeping up with changes in medicine and in Medicaid was wearing her down, she chose to retire her practice rather than "her avocation," meaning her Medicaid work. "I didn't retire until I found a pediatrician whom I thought would treat my patients the way I did. That was Vijaya Malpani."

At 67, Levy wanted to try some new things, do a little more traveling. She went to Alaska and Hawaii, regularly tapes books and newspapers for the Library for the Blind, tutored illiterate adults, and spends time one-on-one with the troubled girls of the department's North Girls Group Home. Often, she would take a girl out for pizza and enable the teenager to air some of the destructive emotion she had bottled up.

"I didn't retire until I found a pediatrician whom I thought would treat my patients the way I did."

"Dr. Levy makes each child feel like the most important person in the world," said Norma Pugh, who worked at the group home. "She



Dr. Levy spends part of her free time making audio tapes of books for the visually impaired.

boosts their self-esteem and is a constant inspiration to me."

More than 300 people attended Levy's surprise retirement party in 1981. It was held at the large pavilion at Will Rogers Park in Oklahoma City and more than 300 of her patients and former patients were there. The volume of food and attendees were reminiscent of Levy's famous chicken dinners and weiner roasts, which she hosted periodically over the years for her Medicaid staff. But this was for her. And, according to Barbara Whittlesey, one of the planners, it was "absolutely wonderful, everything such a party should be."

Children from the early forties, sixties, and eighties mixed and mingled, sharing stories, laughter, and tears. One of the stories Bertha told that day she repeated twelve years later to the audience at another party honoring her. "Like most four-year-olds, this boy's hospital experience was very limited. After an appendectomy, he was put in a ward where there were some infants. A few days later, because he looked worried, he was asked what was his problem. He pointed to the infants and said, 'I know they're going to give me one when I go home and I don't know what I'll do with it.'"

The occasion was the 50th anniversary celebration of the Variety Health Center and she was the evening's top honoree. For fifty years of outstanding volunteer service both as a pediatrician and board member, the center's pediatric clinic had been named for her. She used to hate being singled out for recognition like that, because it almost seemed a corruption of the service. "Sometimes I don't even know why I volunteered for this or that. Call it civic duty... whatever. Sometimes, motive isn't important at all, but doing something constructive is important."

Yet on this evening, March 3, 1992, in a ballroom of the Marriott Hotel in the presence of several hundred persons, Bertha Levy was relaxed. Maybe she had received so many honors and so much acclaim that she was finally getting the hang of it. Or maybe she just decided to let herself go. "Surprisingly, I wasn't embarrassed at all and, in fact, I had a very good time."

At 79, she is still growing.

Begun in 1981, the Leaders in Medicine series honors some of Oklahoma's most outstanding physicians. This is the twenty-fifth article in that series.

Richard Green is a freelancer who has been writing the Leaders biographies for a number of years. Robert Taylor is a freelance photographer. Both are based in Oklahoma City.

The Last Fifty Years in Obstetrics and Gynecology

Robert D. Anspaugh, MD

The last fifty years in Obstetrics and Gynecology have been associated with some of the most outstanding changes in the history of this specialty. We have seen the discovery and use of antibiotics, the Pap smear, shortened hospital stays, the Rh factor, and the birth control pill. It is doubtful we shall ever see as many changes in an equal period of time.

UNTIL 1959, ONLY THREE departments of Obstetrics and Gynecology had not combined.[1] In 1959, Harvard combined their departments, in 1960 Johns Hopkins, and in 1961 the University of Oklahoma became the last university to combine its departments of Obstetrics and Gynecology. Before then, staff meetings had been separate.

When a medical student was first exposed to obstetrics, he was taught the Leopold Maneuver. Standing by the patient's bedside facing the foot, the student determined presentation, the presenting part, and the position of the fetus. He learned that presentation was the relationship of the long axis of the fetus to the long axis of the mother, there being two types, longitudinal and transverse.

He then learned how to do pelvic measurements. Using a pelvimeter, he measured the distance between the iliac crests, the iliac spines, and the external conjugate, which was the distance between the symphysis pubis and the sacrum.

The internal pelvic measurements were then determined by measuring the space between the ischial tuberosities and from the lower margin of the symphysis pubis and the sacral promontory, known as the internal conjugate.

He found there were three types of pelves: the flat, the android, and the gynecoid.

Dr. E.P. Allen made an astute observation when he noted an association between a woman's palatine arch and her pelvic inlet or type of pelvis. This was of importance, since we knew that if a woman had a flat pelvis the head was most likely to enter the pelvis in the transverse position, whereas if she had an android type the head would most likely enter the pelvis in the posterior position. By using this information we could often predict in which position the fetal head would enter the pelvis.

The mechanism of labor was then studied, consisting of descent, flexion, internal rotation, extension, restitution, and external rotation.

I remember attending a meeting at the University of Oregon. The professor asked if I would demonstrate the mechanism of labor to the interns and residents. They obtained a manikin and chamois skin fetus, and I proceeded to explain descent, flexion, internal rotation, extension, restitution, and external rotation. The professor said, "That's fine Bob, just like you taught me at the University of Oklahoma. But do you know what

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we practice now?" I said "No," and he said, "Descent, flexion, section."

One of the residents asked if I could demonstrate forceps rotation in an occiput posterior position, and I proceeded to demonstrate the delivery of an occiput posterior by the key-in-lock, Scanzoni, Bills, and Kielland maneuver. He then asked why more obstetricians did not use forceps and I replied, "I guess because they don't have anyone to teach them."

Until around 1951, all patients were followed during labor by rectal examination, and if a vaginal examination were performed, sterile saline was poured over the perineum. Vaginal examinations were not performed on clinical patients after six months.

L.M.L. episiotomies were used almost entirely in primiparas and approximately 90% of all deliveries were by forceps.

Version and extraction was not uncommon, and manual removal of the placenta became almost routine in the 1950s.

Induction of labor was by quinine, castor oil, and in some cases, intramuscular pitocin. Intravenous pitocin drip was not used until the early 1960s.

Dead fetuses were sometimes induced by placing a rubberized cone-shaped bag in the cervical os; a string was attached to the base of the bag and extended over a pulley at the foot of the bed, where a ¼-pound can of ether was attached. This was known as a Vorhees bag induction.

Anesthesia was ether, nitrous oxide, and cyclopropane.

Home delivery of multiparous charity patients by medical students continued until 1946. In patients who were toxic or a poor risk, local anesthesia was used—and it was more vocal than local. The pain relief was in direct proportion to the ability of the obstetrician to convince the patient she was really not in pain. I recall a new professor of anesthesiology coming to the University of Oklahoma, and I called him to stand by while I performed a cesarean section under local. He said, "May I see you out in the hall?" He then asked, "Don't you think if this patient is too sick for me to put to sleep, she is too sick for you to operate?" And you know, he was right.

"Five minutes sitting in the easy chair in a patient's room is worth twenty minutes with your hands on the doorknob."

—J.B. Eskridge, Jr., MD

Dr. E.P. Allen was one of the fathers of obstetrics in Oklahoma City. He started out doing general practice, but could not make a living, so he moved to Texas. There he had a big practice, but they paid him in meat and vegetables. One day he saw an article in a medical journal where a Dr. De Lee in Chicago was delivering all of his obstetrical patients in the hospital. Dr. Allen then moved back to Oklahoma City and declared himself an obstetrician, saying that if a patient had a complication she would have to go to the hospital. Every patient had a complication.

Dr. Gerald Rogers returned to Oklahoma City in 1937, having trained under Dr. De Lee at the Chicago Lying-In Hospital and he brought Chicago obstetrics to Oklahoma City. Dr. De Lee was an obstetrician with a tremendous respect for infection, and rightfully so, because in those days an episode of childbed fever could wipe out an entire nursery. When he was introduced to someone he would shake hands with himself. He never approved of his house staff putting their hands on a stair railing—a trait Dr. Rogers practiced until he was well along in years.

Dr. Rogers was very meticulous and was seldom the first to accept new ideas. I recall Dr. Earl Bricker, as a resident, asking him why he didn't do something differently, and he replied, "If you can do a thing perfectly, why change?" He was very hesitant to invade a uterus after delivery, and when he did he would first change his gown and gloves and redrape the patient.

Until 1946, all uterine incisions for a cesarean section were horizontal or classical. Then Dr. J.B. Eskridge, Jr., started doing transverse incisions and closing them in one layer. This procedure was slow to be accepted because of fear of injury to the ureters or uterine vessels.

Dr. J.B. Eskridge, Jr., was the

finest obstetrician I have ever known. He was not only an excellent obstetrician and teacher, but he taught me more about the art of medicine than all of the instructors combined.

He bought me a wire recorder, the forerunner of the present-day tape recorder, and whenever I read an interesting article I summarized it on the recorder. Every week we would play the recordings and discuss them.

Whenever guest speakers came to Oklahoma City, Dr. Eskridge would try to get them to come to his home, where he had invited the residents; we would listen to the guests discuss certain articles. I am speaking of physicians such as Drs. Robert Willson, Te Linde, Laman Gray, Eastman, and Woodruff. In later years I ran into some of these physicians, and they would comment on how much they had enjoyed the evening. Some had incorporated the idea into their own programs.

Dr. Eskridge constantly reminded me of the value of making every patient feel as if she were your only patient at that time. He would say, "Five minutes sitting in the easy chair in a patient's room is worth twenty minutes with your hands on the doorknob."

The routine post partum orders for an obstetrical patient in the 1940s were as follows: (1) May elevate the head of the bed six inches on the eleventh day. (2) May dangle on the twelfth day. (3) Out in a chair on the thirteenth day. (4) Home per ambulance on the fourteenth day. Upon going home, patients were to assume the knee chest position for five minutes twice a day to prevent the uterus from becoming retrodisplaced.

Dr. E.N. Smith came to Oklahoma City from Jersey City Lying-In and brought ideas which were somewhat radical to us at the time. He let his patients out of bed on the second day and they could even shower on the third day. He performed median episiotomies on primiparous patients, even putting the scissors in the rectum and cutting the sphincter.

I recall his delivering a patient vaginally who had had a cesarean section with her previous delivery. He was never granted privileges at St. Anthony Hospital, nor was he invited to become a member of the Oklahoma City OB-GYN Society. He was just too far ahead of his time.

When Baptist Medical Hospital opened, only clean cases were allowed on the obstetrical floor. If a woman had delivered and gone home and had a complication, she could not be readmitted to the OB floor. After a year or so, we thought maybe we could safely admit clean D&Cs to the obstetrical floor. We all held our breath but nothing serious occurred. Later we became brave enough to start admitting GYN cases to the same unit and had no regrets.

Dr. Sterling Crawford and I did a study of primiparous breeches delivered during the first five years at Baptist Hospital. We found the cesarean section rate for primiparous breeches was 7.5%, whereas it was 4% for cephalic presentations. Now the national average is 30%.

In 1958, Drs. Pincus, Rock, and Garcia introduced the birth control pill and brought about one of the biggest changes in obstetrics and gynecology. The pills are the most widely used means of contraception and more is known about their epidemiology than any other drug put in the human mouth. They also have cut down on the incidence of ovarian cysts and carcinoma of the uterus and ovaries.

The Oklahoma City Obstetrics and Gynecology Society was formed in the early forties. One of its main purposes in formation was to establish a group where young physicians in the specialty could present new ideas for consideration. My first presentation was a study on endometrial biopsies and was the first paper presented on this subject at the Central Association of Obstetricians and Gynecologists in St. Louis. At the time of the presentation in Oklahoma City, there was some doubt as to whether it would ever compete with a formal D&C.

My second study was on the administration of Rh antibody serum to Rh negative women

Most gynecological surgery, other than injuries resulting from childbirth, was performed by general surgeons.

during pregnancy. In the mid-fifties, Ortho Pharmaceutical Corporation would perform Rh antibody titers on Rh negative mothers during pregnancy. Then a decision could be made as to whether an early delivery and possible blood transfusion should be given to the newborn infant. I heard about a friend of mine in St. Louis who was making his own Rh antiserum.

At that time Governor Edmondson's wife had delivered a stillborn infant as a result of having received three units of her husband's Rh positive blood several years prior to her pregnancy. We drew blood from her on several occasions, and Dr. Dewar, the head of pathology at Baptist Memorial Hospital, made our Rh antiserum.

The third presentation, made with Dr. William E. Hood, concerned using a suprapubic catheter following vaginal surgery. We used a No. 11 needle to enter the bladder abdominally and inserted an infant feeding tube. The needle was then removed, leaving the tube in the bladder. The tube was removed when the patient could void satisfactorily when the catheter was clamped off.

I presented this paper later at the Continental Gynecologic Society in Florida and a friend of mine, Dr. Layman Gray, said he was not convinced, but would give it a try. One year later he wrote me that he had performed this procedure in 23 cases and felt it was a good method.

Most gynecological surgery, other than injuries resulting from childbirth, was performed by general surgeons.

The most common pelvic operation performed in the forties was a uterine suspension. The numerous indications included sterility, backache, dysmenorrhea, and pelvic congestion syndrome. Presacral neurectomies were often performed at the same time for dysmenorrhea and endometriosis.

Pelvic congestion syndrome was described as a generalized edema of the pelvic organs as a result of varicosities of the vessels of the broad ligament. The diagnosis was usually made when movement of the cervix elicited pain in the pelvic region.

In cases of uterine descensus, the uterus was occasionally sutured to the abdominal wall.

The Watkins Interposition operation became popular during the time span when gynecologists became more numerous. An incision was made transvaginally in the anterior cul de sac and the uterus was pulled through and sutured to the descending pubic rami, thus having the bladder rest on the top of the uterus.

Dr. Henry Bennett occasionally performed a Richardson composite operation, which consisted of removing the lower portion of the cervix, then opening the anterior cul de sac and removing the uterus at the cervix-uterine junction. This left a ring of viable tissue which was then sutured up in the pubic angle to prevent prolapse. The vaginal mucosa was then closed as a vaginal repair.

A partial or complete colpocleisis was more frequently performed in women with a prolapse of the uterus. In the partial operation, or Le Forte colpocleisis, the middle portion of the vagina was closed, leaving two small openings lateral to the closure.

The complete colpocleisis was performed by placing concentric sutures around the vagina from the apex to the introitus, thus leaving no vagina.

Almost all hysterectomies were of the subtotal type, but prior to opening the abdomen the patient was put in the lithotomy position and extensive cautery was performed using a cautery which resembled a small soldering iron. The entire cervical os was destroyed up to the level of the internal os. When the uterus was removed you could see the burned area made by the cautery. This was an attempt to destroy all of the cervical glands and endocervix.

This was not as bad as it sounds, as Dr. Bela Halpert, the professor of pathology, and I reviewed all of the cases of cervical stump carcinomas at the University of Oklahoma Hospital

Everybody scrubbed for ten minutes by the clock.... One day I was in a hurry and I scrubbed and held out my hand for a towel and the nurse said, "You only scrubbed eight minutes; go back and scrub two more."

and we found none who had had this treatment of the cervix preoperatively.

Before the 1960s, bleeders were clamped with a hemostat and then tied with catgut. This was time consuming, and when we changed to cautery considerable time was saved.

You could go into the living quarters of any hospital and see long strings of catgut knots where the house staff had been practicing their knot tying.

In 1942, Pap smears came into use and brought a tremendous reduction in the incidence of carcinoma of the cervix. At University Hospital in the 1940s, carcinoma of the cervix was treated by inserting radium needles into the cervix and a uterine tandem in the fundus; this was then followed by x-ray therapy.

Carcinoma of the uterine fundus was treated with a uterine tandem containing radium. This was followed by x-ray to four or six fields. The gynecological resident calculated the dose of radium and x-ray for each case. Six weeks after completion of the radiation therapy an abdominal hysterectomy and bilateral salpingo-oophorectomy was performed.

Dr. Wendell Long was the first gynecologist in Oklahoma City to start doing routine total hysterectomies in the early forties. I remember a physician asking him why more doctors did not do total hysterectomies and he replied, "Two reasons—the right ureter and the left ureter."

He was without doubt the finest gynecologist I have ever known. He was an excellent diagnostician, surgeon, teacher, and gentleman, and an immaculate dresser. He never had his nurse call another physician on the phone; he did it himself. I remember once he called me on the phone when I was an intern, and he had to wait until they could locate me. I asked him why he didn't have his nurse call me and his reply was, "You are a doctor." Today a nurse often calls and asks you to wait for her doctor because he is busier than you are. How times have changed.

An agreement was reached between the departments of gynecology and surgery whereby the gynecologists would not do any breast surgery if the general surgeons would not do any pelvic surgery; it has worked out very well for both groups.

When I first began assisting Dr. Long as an intern in 1942, he scared me to death, as he would often tap you on the back of your head to get your attention. Some assistants took offense at this and did not want to scrub with him, but I realized it was my fault for not anticipating what he wanted. I assisted him every time I had the chance as an intern, and later as a resident.

I remember one day we had a particularly difficult case, and he asked me to close the abdomen. When I finished he was waiting for me in the dressing room. He put his arm across my shoulders and said, "Dr. Anspaugh, anything that happens in the operating room is forgotten when the surgery is finished. Are we still friends?" I said, "Yes, Dr. Long, but when other doctors want me to do something, they say so; they don't tap me with an instrument."

He replied, "I guess it's just the Indian in me; I don't talk much, but Dr. Le Roy and I would like you to join us in private practice when you finish your residency." However, he died at the age of 46 and I joined Dr. J.B. Eskridge, Jr.

Dr. Le Roy Long, Sr., was the dean of the O.U. Medical School, and he had two sons, Le Roy, Jr., and Wendell. They resigned from the staff at the university when Governor Bill Murray wanted chiropractors admitted to the teaching staff.

Sulfanilamide came into use in the 1930s. I recall reading an article on the train on my way to start to medical school; it was about a new drug called sulfathiazole, which was anticipated to change the practice of medicine. Anytime you removed an appendix or uterus, you sprinkled sulfanilamide crystals beneath the peritoneum. I remember being called on several occasions by a floor nurse saying the patient we had operated on the day before had a good pulse and blood pressure, but was cyanotic. We later realized that this was sulfmethemoglobinemia.

Penicillin was first used in Oklahoma City in 1943 on a young

boy who was dying of osteomyelitis. We gave him 15,000 units of penicillin every three hours, and 48 hours later his temperature was normal.

Everybody scrubbed for ten minutes by the clock and then went through alcohol and sterile water. One day I was in a hurry and I scrubbed and held out my hand for a towel and the nurse said, "You only scrubbed eight minutes; go back and scrub two more."

Anesthesia was mainly cyclopropane and spinal. Several of the surgeons administered their own spinals, and a nurse would occasionally check the blood pressure and vital signs.

When Baptist Memorial Hospital opened it was decided to limit privileges according to the physician's training. This was the first hospital to limit a physician's privileges. Prior to this time, a physician could do anything where he felt capable. I can remember gynecologists who set fractures.

An agreement was reached between the departments of gynecology and surgery whereby the gynecologists would not do any breast surgery if the general surgeons would not do any pelvic surgery; it has worked out very well for both groups.

Dr. Milton Serwer started doing peritoneoscopies in the early forties, but they had a very limited use as there was no secondary or operating probe; their main use was in looking for metastatic lesions.

In the 1950s the colposcope was introduced whereby a scope was inserted through the cul de sac with the patient in the knee chest position. It offered some advantage over the peritoneoscope, but, again, there was no secondary probe.

"My grandson will probably tell his friends that his grandfather could remember the day when you opened the abdomen to do a hysterectomy."

—Layman Gray, MD

With the introduction of the laparoscope, a whole new field was opened. I remember watching a laparoscopic-assisted vaginal hysterectomy at a meeting. Dr. Layman Gray was sitting next to me, and at the completion he said to me, "My grandson will probably tell his friends that his grandfather could remember the day when you opened the abdomen to do a hysterectomy." There are still a number of gynecologists who feel as if the laparoscopic-assisted vaginal hysterectomies are for the gynecologist who does not have enough experience in vaginal hysterectomies.

In a recent study published by *Ob Gyn Surgery,*[2] physicians were doing laparoscopic supra-vaginal hysterectomies abdominally and doing an extensive cauterization of the endocervix, thus cutting down the risk of cervical carcinomas.

In order for a gynecologist to have Type I privileges, he or she must be board certified or board eligible. There were a few who had Type I privileges under what we called the Grandfather Clause, but I don't believe any are still practicing under that rule.

In summary, I believe the two outstanding events in obstetrics and gynecology in the past fifty years have been the introduction of antibiotics and birth control pills.

In conclusion, I hope in the not too distant future it will be possible for a woman to deliver breech presentation by the vaginal route.

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An Alternative to Hospital-Dominated Groups

Charles Bond, JD

Has your hospital approached you or your colleagues to form medical groups that are tied to hospital-controlled management services organizations (MSOs) or affiliated with hospital-linked APAs, HMOs, or contracting committees? If they have, stop, look, and listen. California has seen a virtual tidal wave of hospital efforts to bring physicians under their control and capture their patient bases.

Before signing any hospital-initiated proposal, consider its terms very carefully: You might be signing away your practice and your future, and there are better alternatives. One alternative is for physicians to take the future into their own hands by affiliating with a pro-physician MSO that answers their needs and preserves the sanctity of physician-patient relationships.

Hospital MSOs Aren't the Answer

Do not be surprised if your hospital exerts considerable pressure to create an "integrated health system." Hospital tactics for forming captive groups are strikingly similar from institution to institution. Administrators solicit and, in some cases, pay for key medical staff members' support. In turn, these physicians—without necessarily disclosing that they are shilling for the hospital--recruit other group members. Administrators also use high-pressure tactics and promise special hospital benefits to founding members. One administrator recently told potential group members that, "It's five to midnight and the bar is closing, so you'd better sign up." Often, hospitals discourage physicians' specific questions. Physicians intimidated or paid by the administration fall into line and encourage others to do so quietly. Physicians who ask too many questions are not invited to future meetings.

Yet, questions are in order. Hospital-based MSOs frequently ask physicians to help fund the operation's start-up by buying stock in the group's new professional corporation and signing over to the group their current practice assets, including their accounts receivable. The hospital-based MSO takes over the physicians' scheduling and their contracting with third-party payers, thereby taking total control of their income-producing capacity. If the hospital controls when physicians see their patients, which patients they see, and the amount of reimbursement, what is left of the physicians' practice? In effect, physicians are "selling" their practices' assets. patient base, and control to the group, while retaining their overhead obligations. and paying potentially tens of thousands of dollars for the privilege.

California physicians should understand the potential consequences of signing over their practice management and contracting powers to a hospital controlled entity.

A Fundamental Conflict of Interest

There is an inherent conflict of interest between the hospital's administrative concerns and physicians' concerns. Hospital-controlled MSOs will naturally seek contracts that maximize hospital profitability, possibly at the expense of group profitability. For example, if the hospital can negotiate a higher reimbursement per diem for in-patient admissions by offering lower physician reimbursement, is there a question of how the physician group will fare in the negotiations? If physician groups remain independent, however, they can negotiate freely to form and reform affiliations as mar-

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ket conditions change, even creating regional physician networks that might be impossible if the group were tied to a single hospital. Physician flexibility and independence in the marketplace are obviously what hospitals do not want.

There are potential conflicts between hospitals and physicians over the growth of hospital-controlled groups. For example, every time the group expands, not only is the patient-base diluted (i.e., more competition within the group for managed care patients), but the individual group member's equity (i.e., the value of their shares) also is diluted. Although some groups might guarantee founding members that the group will not expand for a year or two, the commitment is insignificant in the long run. There are usually no provisions preventing the hospital-controlled group from eventually bringing in more and more physicians.

Physicians should recognize that in the future it will be economically more important for the hospital to bring new physicians into the group to expand their patient base than it would be to protect the economic well-being of physicians already in the group. In other words, physicians should expect hospital-controlled groups to expand to serve the hospital's interests, not necessarily the physicians' interests.

Takeover Without Compensation

Physicians should also consider the possible impact of hospital control over their private-payer mix and their "traditional" practices. As hospital-based MSOs use their contracting and scheduling power to exercise more control over individual physicians' patient mix, any vestiges of their private practice would be eroded and eventually lost altogether. Then what would physicians have left if they wanted to withdraw from the group?

A surprising number of hospital-sponsored groups make little or no effort to evaluate each physician's practice; they form the group on the premise that all practices are of equal value, issuing the same amount of stock to each group member at the same nominal price. Obviously, all practices are not equal, but to speed up and "simplify" the group formation process, the hospital urges physicians to accept this equal evaluation formula. The shortcut might be simple going in, but what if a physician wants to get out?

Physicians also should be wary of termination provisions. Many hospital-backed contracts provide for physician termination without cause with three to six months' notice. So, after capturing the physician's patient base, the hospital-controlled MSO can cut the physician loose with a pittance and no practice. At a minimum, therefore, physicians should insist that the MSO evaluate their practices at the time of contribution to the group and agree upon a buy-out formula in advance with written guarantees sufficient to compensate the physician for the practice. In addition, physician termination should be for cause, with adequate rights of appeal.

Even provisions for voluntary withdrawal or retirement from the group are often unfavorable to physicians. Usually the terminated, withdrawing, or retiring physicians are guaranteed little or no payment for the practice they are leaving behind. Some programs guarantee only stock buy-back at the original purchase price, (which is usually a nominal sum) without reimbursing physicians for their accounts-receivable contributed or their accounts-receivable earned for the group, not to mention the value of the physician's original patient base.

Sharing Financial Projections

In recruiting physicians, hospitals generally do not share any of the hospital's financial projections for the group (if any exist) with potential physician members. Hospitals often circulate entire documents bearing such titles as "Business Plan" and "Prospectus" that contain no projection of potential physician income or the MSO's expected management costs. Many contracts provide for additional withholding from physicians' future earnings (typically $15,000 or more) to cover unforeseen expenses. The MSO does not assume or pay for the physicians' liabilities (such as office rent, telephone, or other overhead). At the same time, the hospital offers no guarantees for physicians' future income.

In some instances, future expenses remain vague because the MSO does not reveal the terms of contract with the hospital-controlled MSO until after the group is already irrevocably formed (i.e., after physicians have transferred their practices). At that point, physicians who do not like the deal have no choice but to remain or to leave the group with no practice. It goes without saying that any physician contemplating an alliance with a hospital-controlled MSO should first find out the contract's precise terms.

The Need for Legal Advice

Physicians who are approached by such an MSO should seek independent legal advice, and in selecting their own attorneys, physicians should choose recognized, experienced, pro-physician counsel. Normally, hospitals offer to furnish an attorney to the group rather than to the individual physicians interested in joining

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the group. Without exception, the attorneys hired by hospitals to form these captive groups have long represented hospitals and are not historically physician-friendly. Hospitals do not often disclose the potential conflict of interest and place little emphasis on the ethical rule requiring lawyers to advise parties forming a new business—which is what a group is—of their right to separate representation.

Physicians need their own counsel in such transactions. The decisions and contractual relations in these transactions are too complex and too significant for physicians not to have the benefit of individual legal and accounting advice.

A New Alternative: The Physician-Focused MSO

An important alternative to hospital-initiated efforts is evolving: a management services contract offered by physician- oriented and physician-friendly MSOs. One such organization, based in Berkeley, Calif., but offering services statewide, is "Physicians' Advocates." As its name implies, Physicians' Advocates is dedicated to preserving physicians' independence by helping them create well-managed groups that meet hospitals and third-party payers on an equal footing.

Pro-physician MSOs are not controlled by any hospital or third-party payer. Dedicated to physicians' independence, they succeed only if the physician groups they manage succeed. They offer "soup-to-nuts" services for physicians forming and running groups:

- Assistance in forming the group, including model legal agreements and practice evaluation for all incoming group members
- Acquisition of, and contracting for office space, equipment, and supplies for the group practice
- Hiring of office personnel and contracting for support services, such as billing, accounting, and scheduling
- Retirement and benefit services arrangements for providing access to capital for group expansion or buy out of retiring partners (after a minimum number of years of service)
- Perhaps most important, expert contract negotiation with third-party payers and hospitals, including tracking of managed care contracts to determine profitability

In short, the physician-oriented MSO will take over the headaches of forming and running the group practice, so that all physicians have to do is treat patients and rotate on reasonable call.

Physician-Friendly MSO Benefits

What are the benefits of the physician-oriented MSO as opposed to the hospital-sponsored foundation, group, or MSO? First and foremost are loyalty and accountability. Physicians are the natural guardians of, and advocates for, good patient care and should align themselves with their patients' interests. The physician-friendly MSO facilitates this role. In the systems of the future, with their disincentives to diagnose and treat (e.g., in capitated managed care, HMOs, etc., where profit is enhanced by withholding patient care), physicians will inevitably face a conflict between patient well-being and the entity's monetary interests. Conflicts between physicians advocating proper patient care and third-party payers seeking to limit expenditures already are skyrocketing in number and severity. If physicians surrender control of their practices to hospital-oriented managers, who will stand up for the patient? The question of hospital-versus-physician control of medicine goes to the heart of what our society expects of its healers, and more importantly, what physicians expect of themselves.

Although physician-friendly MSOs' principal motive is to allow physicians to control their practices and their patient care, the hospital-controlled group's principal motive is to capture the physician's patient base. Primary care physicians are the hospital's particular targets. The hospital's purpose in creating the group is to co-opt physicians' contracting power and to control their ability to schedule patients. Ultimately, if physicians cede those powers to the hospital, they will become wholly dependent on the MSO for their livelihood. Hospital-controlled groups make little or no provision for the physician's future. Generally speaking, such groups are not particularly interested in group physicians' long-term well-being, their personal qualities, or their medical skills. Hospital MSOs' main concern is physician patient base size.

By contrast, physician-oriented MSOs provide organizational and management services to help physicians form and run groups, but are dedicated to physician independence. Such MSOs are designed to help those physicians who do not want to be tied to one hospital, but would rather have the freedom to be an equal player in future health care negotiations. Indeed, as health care becomes regionalized, physicians who are too closely linked to a single hospital might be at a disadvantage.

Physician-oriented MSOs have a critical structural difference as well. They are not backed by hospitals, so they depend on physician investment and the value of their services. In other words, physician-oriented MSOs succeed only if their physician groups succeed, and so, like doctor-owned insurance companies, are prime examples of physicians controlling their own destiny.

Groups Necessary for Survival

In the face of reforms that the Clinton administration no doubt will propose and Congress ultimately will pass, physicians need to position themselves to survive. Most physicians cannot turn the clock back or, as so many wish, just hold on for a few more years. The driving engine of change is upon us. With Medicare capitation and the continuing shift to managed care, physicians—even those already in groups—need to look at their practices' structure to see if they will be viable in the new economic environment.

Physician-focused MSOs offer physicians the means to end the cottage industry model of medical practice: Private practitioners who face ever-increasing overhead and ever-decreasing reimbursements need little convincing that small offices with redundant systems, personnel, and other overhead costs are not the most efficient, cost-effective, or profitable form of practice. Physicians need the economies of scale offered by medical group participation: They need the consolidation of support services (such as billing and scheduling), and the discounts of group purchasing.

Physicians also need the sophisticated management that only a group can afford. As intelligent and capable as physicians generally are, all their years of medical training do not include a whit of management, accounting, or business education, and little, if any, health care economics. Furthermore, the style of decision-making that works so well in treating many patients in a short time (rapid assessment based on key indicators) is not the same style used by experienced business managers. Physicians are trained to take care of people, not balance sheets.

Finally, physicians need the contractual clout that only a group can provide. Physicians have far more power than they realize to direct the country's future health care choices. After all, physicians are the patient's point of contact—not only with the medical system (physicians direct clinical and diagnostic choices), but with the reimbursemsent system as well (physicians act as patients' intermediary, documenting and justifying reimbursement for their care). As Russell C. Coile, Jr., a futurist normally associated with hospital planning, wrote in the preface to his book, *The New Medicine: Reshaping Medical Practice and Health Care Management:*

"Doctors are at the pivot point when it comes to changing tomorrow's health system. Hospitals are re-

treating from marketing health services on the retail model. They made an important discovery about health care marketing in the 1980s: Physicians still control patients and drive the health system. That fundamental truth is becoming widely recognized by hospitals, insurance companies, managed care plans, and government officials. All reforms to be made in tomorrow's health industry will involve changing physicians' behavior. Physicians occupy the high ground at the mouth of the channel, and any alterations of the U.S. health system must take this into account."

Thus, physicians have enormous power and should meet hospitals and third-party payers as equals, not as supplicants. Physicians can only do that in groups with sufficient size and management savvy.

An Important Business Decision

Physicians face what is probably their professional career's most important business decision: whether to turn control of their practice over to a hospital-based group or to a physician-oriented organization. As hospitals see their economic bases eroding (by such trends as more outpatient surgery, shorter lengths of stay, DRGs, and other fixed payment forms), it is no wonder that they are trying to absorb medical practices through the formation of captive medical groups. Physicians should beware of these entities' pitfalls and should consider instead forming their own independent medical groups and acquiring the professional management help they need through physician-oriented MSOs.

A good, pro-physician MSO should offer physicians the following services:

- A clear business plan that spells out the relationships of all the players
- Practice evaluations for all incoming group members
- Model legal documents access to capital access to necessary physical assets
- Skilled day-to-day practice management
- Personnel hiring
- Billing and accounting services
- Group scheduling
- Expert, pro-physician reimbursement negotiation, coupled with a system to track contract profitability

Above all, the physician-oriented MSO should offer physicians an attitude dedicated to physician empowerment in the interest of good patient care.

The Author
Mr. Bond is an attorney with Charles Bond & Associates, a Berkeley, Calif., law firm. He has represented physicians' interests for more than 18 years.

LETTERS

■ Sauce for the gander?

Replying to an inquiry about using the existing federal employees health care benefits plan as a model for a new plan in Oklahoma, AMA Executive Vice President James S. Todd, MD, wrote the following to OSMA Executive Director David Bickham:

I appreciated your recent letter regarding health system reform. In recent months, we have devoted a substantial amount of time and resources to health system reform, both on the national and state level. Obviously, the primary focus of our efforts has been on President Clinton's health system reform proposal. As you know, although we applaud the President's dedication to reforming our nation's health care system, we feel that proposal might endanger both physicians' and patients' freedom of choice. Over the weeks and months ahead, we will continue to work closely with the Administration on this proposal, as well as with Congressional leaders as they begin their debate over this complex issue.

You are correct in noting that the AMA and other groups have agreed that certain aspects of the Federal

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Employees Health Benefits Plan are exemplary. However, that program does not provide for a complete structure for reforming our national health system, insofar as it is paid for and administered by the federal government. Fundamental issues that arise when fashioning a comprehensive reform system, such as the financing mechanisms for the plan (i.e., employer mandate, taxes, etc.) are not addressed by FEHBP.

We support certain components of FEHBP—for example, it provides federal employees with a choice of health care plans, including a fee-for-service option, with cost-sharing to encourage responsible health care decision making. However, FEHBP has not been successful at controlling rising costs, which are reflected in increasingly expensive premiums. In addition, although several plans participate in FEHBP, there is little competition among plans due to a virtually guaranteed continued slot for participating plans.

In sum, although the AMA continues to analyze the FEHBP and other existing programs such as CHAMPUS in order to draw from their experiences, we continue to advocate in favor of those comprehensive health system reforms found in Health Access America, including an employer mandate and significant insurance reforms. The positive components of FEHBP can be incorporated into the structure of health purchasing alliances under a federal reform scheme based on the managed competition construct, such as the Clinton proposal and various other proposals that Congress will consider.

Again, thank you for your thoughtful input on these issues. If the AMA can provide any assistance to the Oklahoma State Medical Association on health system reform issues, do not hesitate to contact us.

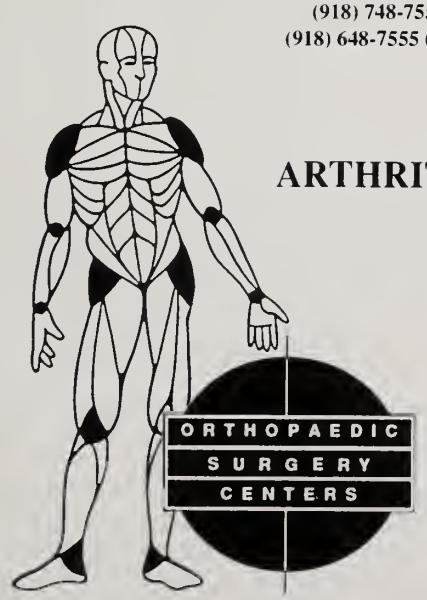
—James S. Todd, MD
AMA Executive Vice President

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Call for Papers

1994 International Conference on Physician Health
September 16-20, 1994. Ottawa, Ontario, Canada

"Stress: The Profession, the Family and You"

The 1994 International Conference on Physician Health, co-sponsored by the American Medical Association, the Federation of State Medical Boards, the Canadian Medical Association, and the Federation of Medical Licensing Authorities of Canada is scheduled for September 16-20, 1994, at the Ottawa Westin Hotel.

Ottawa is Canada's capital and offers many national museums, over 60 miles of bicycle paths, hiking in Gateneau park, squash courts and swimming at the hotel and golf nearby.

The conference will provide a forum for practitioners and researchers to present recent findings and innovative treatment and education programs in physician health. This conference will address a range of issues, such as AIDS, HIV, problems related to aging, mental illness, substance abuse and physical disabilities and limitations, including those caused by general medical conditions. Possible topics for presentation include: presentation and treatment of health problems among physicians, the impact of disorders on physicians' families and practices, medical-legal issues facing hospital administrations and licensing boards, and material on health promotion and disease prevention. *Abstracts which address issues related to these topics (i.e., prevention, diagnosis, treatment, rehabilitation), but not dealing specifically with physicians are also welcome.*

Three types of presentations regarding these physician health issues are invited:

- **Poster Presentations**
 Written presentations of data-based research, epidemiological research, or program descriptions.

- **Paper Sessions**
 Oral presentation of scientific, data-based findings relative to the topic of physician health.

 Abstracts for poster presentations and paper sessions should contain an introductory statement on the significance of subject matter. Description of methods, results, and conclusions should follow the introductory statement.

- **Workshops**
 Training or instructional presentations, designed to improve specific skills of persons who work in the area of physician health.

 Abstracts for workshops should contain information on the program's intended audience, goals, teaching strategies, and materials. Evaluation data should be summarized

Abstracts may not exceed 200 words. Any abstracts exceeding that length will be rejected. Abstracts should be typed, double spaced, and mailed (not faxed). Four copies of the abstract should be sent, along with one self-addressed, stamped envelope. All submissions must list the primary and secondary authors and their professional affiliations. Telephone number and address of primary author must also be included.

Submissions *must* be received by February 1, 1994.

Abstracts will be submitted for blind review. Abstracts will be judged on their applicability to the conference topic area and their scientific merit. The decisions of the blind reviewers will be communicated to the abstract's primary author by April 1, 1994.

All presenters are expected to register for the conference at the AMA member rate. We are unable to provide any financial support for presenters. Presenters will also be responsible for their own transportation and hotel expenses, as well as making all reservations for same.

Send all materials to:
Elaine M. Tejcek, Physicians Health Foundation, American Medical Association, 515 N. State Street, Chicago, IL 60610.

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■ Of pain and patients

To the Editor: This note is a congratulatory effort for your editorial ["Awesome Duty"] in the August issue of the OSMA JOURNAL. Your final sentence emphasizing that physicians should not be afraid of prescribing controlled medication is a key statement that bears a great deal of emphasis in my judgment. I'm appalled at what happened to Jack Enos. I am deeply concerned that whether they intended it that way or not, the Oklahoma Drug Enforcement Agency and the Oklahoma Board of Medical Licensure is in the business of "thought control." In a subtle way, by their treatment of Dr. Enos and by some of the public statements that have been issued by the board, there is a continued emphasis to physicians to be ultraconservative and negative on the subject of analgesic prescriptions.

My perspective is that if I were going to err when prescribing analgesics and controlled drugs, I would err on the side of the patient. In this way, I would never be guilty of unwittingly increasing patients' pain and suffering. In the current environment, I suspect that physicians will increasingly err on the side of their own safety from the police forces of the DEA and the Oklahoma Board of Medical Licensure and Supervision. Fear of the consequences will enter into the equation of deciding what's best for a patient.

It's probably an exaggeration, but it's the same sort of thought control that enabled some of the bad things that happened in Europe to occur when ordinary citizens and professionals were fearful of defying the leadership and thus permitted evil to occur.

These particular chaotic thoughts of mine represent my irritation with what happened to Jack Enos. I am assigning myself the responsibility of developing another "commentary" in the near future. I plan to assemble medical literature indicating that physicians do a poor job of controlling pain because of the fear of consequences from the Drug Enforcement Agency and many physicians mistakenly thinking that NSAIDs are effective analgesics and much "safer" than the ordinary analgesics.

Pharmaceutical advertising contributes to this flawed thinking. I wonder if the Board of Medical Licensure is aware of the fact that the second most common cause of emergency hospital admissions for Medicare patients is gastric bleeding secondary to NSAID therapy. Rather than censure excellent physicians like Dr. Jack Enos, the board would do a better public service by becoming more knowledgeable on the subject of pain management in patients with chronic painful problems.

(continued)

In Memoriam

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Joseph Reid Henke, MD	September 28
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John Frederick Kuhn, Jr., MD	November 11
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Maud Staveley-O'Carroll, MD	January 16
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Emma Jean Anthis, MD	September 27
Russell D. Harris, MD	September 28
Walter Lee Honska, Jr., MD	October 9
Ethel Maurice Walker Heras, MD	October 25
James Burton Pitts, Jr., MD	October 29

In any case, I appreciate your thoughtful editorials and willingness to present scientific thinking in a delicate and intelligent fashion that hopefully will be read by the addressees.

—John A. Blaschke, MD
Oklahoma City

■ About that 'advertisement'...

To the Editor: I am in receipt of the October 1993 JOURNAL of the Oklahoma State Medical Association. On page 496 is an article on initial experience with single lung transplant in Oklahoma. I am really resentful that an article would appear in the JOURNAL as a paid advertisement of this sort. I feel that this does the credibility of the JOURNAL a great deal of harm.

I have lived in Oklahoma now for three years and have found, in general, the JOURNAL of the Oklahoma State Medical Association to be a good journal. I feel, however, that this sort of article really cheapens the reputation and the stature of this journal.

I thought I should sit down and share with you my feelings upon receipt of the JOURNAL. I would hope that in the future, this will not be a continuing method of advertisement, nor a way of selling a product.

—Russell J. Green, MD
Claremore

HEALTH DEPARTMENT

Protect your medical office staff from the patient with TB

The transmission of tuberculosis (TB) can occur in any health care setting, particularly those providing care for persons who are at high risk for TB, such as: Persons with HIV infection; residents of nursing homes, foreign-born persons and alcoholics.

The Centers for Disease Control and Prevention (CDC), recommends the following specific actions to prevent the transmission of TB in medical office settings:

1. Ensure that all employees, particularly those with direct patient contact, are properly screened for TB using the Mantoux skin test upon employment, and annually.

2. To prevent transmission of TB in a medical office, persons with active infectious TB must immediately be identified and isolated. Staff members who have first contact with clinic patients, such as receptionists, should be trained in identifying persons with potential TB. Any adult patient with a cough (of more than two weeks duration, with no known cause) upon entering the medical office or clinic, should be given a disposable particulate respirator (a special type of mask) and placed in an isolation room. Persons with known or suspected TB should never sit in waiting rooms.

3. Any patient with symptoms consistent with T13 should be immediately skin tested for TB using the Mantoux technique. Skin tests should be applied and read by experienced health care workers.

4. If skin tests are positive, appropriate medical follow-up consisting of medical history, chest x-ray, and sputum examinations should be performed immediately. Sputum specimens should be sent to a laboratory that uses the rapid identification techniques which give results in 7 to 10 days rather than 1 to 2 months (the Oklahoma State Department of Health laboratory provides this service without charge).

5. Appropriate treatment, either preventive or curative, should be started on all identified persons as soon as possible. Possible infection with drug-resistant strains of TB needs to be considered prior to treatment.

TB medical consultants are available Monday through Friday at (405) 271-4060. All persons with TB disease and infection should be reported immediately to the state health department to ensure appropriate follow-up and treatment of potentially exposed persons.

Although the complete elimination of TB transmission in medical office settings may not be possible, following the above guidelines should help to minimize the risks.

For more information, contact the Oklahoma State Department of Health Communicable Disease Division at (405) 271-4060. ℑ

Note: RE "Animal Bite Update" [HEALTH DEPARTMENT, Sept. 93]. Dogs and cats are required to be placed in quarantine following a bite to a human. Other animals, including cows, ferrets, horses, sheep, skunks, raccoons, etc. cannot be placed in quarantine; these animals must be euthanized and tested to determine if they have rabies.

Deaths

Emma Jean Anthis, MD
1907 - 1993

OSMA Life Member Emma Jean Anthis, MD, retired Healdton general practitioner, died September 27, 1993. Dr. Anthis was born in Mounds, Indian Territory, and attended Muskogee schools. She earned both her bachelor's degree and her MD from the University of Oklahoma, graduating from the School of Medicine in 1933. In 1934 she established a medical practice in Wilson, Oklahoma, and in 1939 she moved the practice to Healdton.

Ethel Maurice Walker Heras
1909 - 1993

Dr. Ethel Walker Heras, an OSMA Life Member, died October 25, 1993, in Keene, Texas. A native of Seattle, Dr. Walker earned her medical degree at Loma Linda (Calif.) University School of Medicine in 1936. She moved her general practice to Oklahoma in 1946, practicing first in Ardmore and later in Jay, Harrah, and Marietta. She was granted Life Membership in 1986.

Walter Lee Honska, Jr., MD
1926 - 1993

Stillwater physician Walter L. Honska, Jr., MD, died October 9, 1993. Dr. Honska was awarded Life Membership in the OSMA in April of this year. Born in Tulsa, Dr. Honska was graduated from the University of Oklahoma School of Medicine in 1954. He had a private practice in internal medicine and was a former clinical instructor at University Hospital and clinical assistant at the Veterans Administration Hospital in Oklahoma City.

James Burton Pitts, Jr., MD
1918 - 1993

James B. Pitts, Jr., MD, Oklahoma City obstetrician-gynecologist, died October 29, 1993. An OSMA Life Member, Dr. Pitts was born in Carterville, Missouri. He was graduated from the University of Oklahoma School of Medicine in 1946 and after completing his internship, entered the U.S. Army during the occupation of Japan. In 1953 he returned to Oklahoma City, completed his ob-gyn residency, and established his practice. Dr. Pitts was very active in organized medicine and in 1981-82 was president of the OSMA. He was also a past president of the Oklahoma City Ob-Gyn Society and the Oklahoma County Medical Society. He chaired the OCMS Grievance Committee, was both alternate delegate and delegate to the American Medical Association, and was a trustee of the Alumni Association of the College of Medicine. He served on the boards of the Oklahoma Foundation for Peer Review, the Physicians Liability Insurance Company, and the OSMA.

Classifieds

Classified ads are 50 cents a word, with a minimum of $25 per ad. A word is one or more characters bounded by spaces. Box numbers will be assigned upon request and will add 6 words to the total. Payment must accompany all submissions. **Orders will NOT be accepted via telephone or fax.** Mail ad with payment to OSMA JOURNAL, 601 Northwest Expressway, Oklahoma City, OK 73118. Deadline is the first of the month preceding the month of publication.

Physicians Wanted

FAMILY/GENERAL PRACTICE PHYSICIANS - Northwest Kansas community, Atwood, Kansas offers many opportunities to raise a family in a healthy lifestyle, and stable, yet economically sound environment. Excellent clinic facilities, outstanding benefits and call schedule. Call Jeffrey Bensman at 1-800-638-6942.

Internist (Primary Care/Cardiology) seeks long term attractive opportunity where real need and community support exist. Write Box 45, c/o OSMA Journal.

Southern Plains Medical Center, 33 physician multispecialty group in Chickasha OK currently needs BC/BE UROLOGIST, OB/GYN, FAMILY PRACTICE PHYSICIAN, and an ANESTHESIOLOGIST. Located 35 miles southwest of Oklahoma City on Interstate 44 in a family oriented college community of 17,000 with service area of 110,000 population. Outstanding medical center with ambulatory surgery center. Next door to 156 bed regional hospital. Excellent guarantee and benefits. Contact Jeanie Bledsoe, Recruiting Coordinator, Southern Plains Medical Center, 2222 Iowa, Chickasha OK 405-224-8181.

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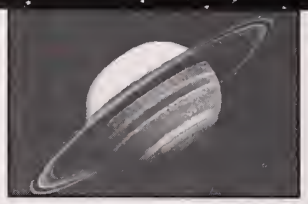
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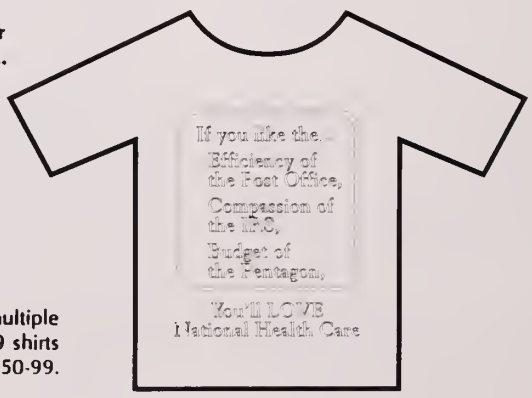
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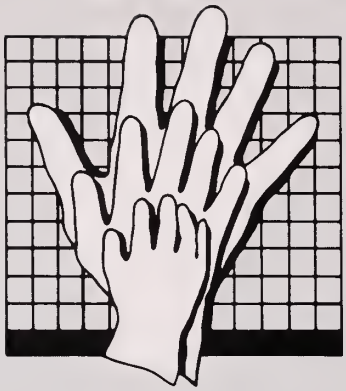
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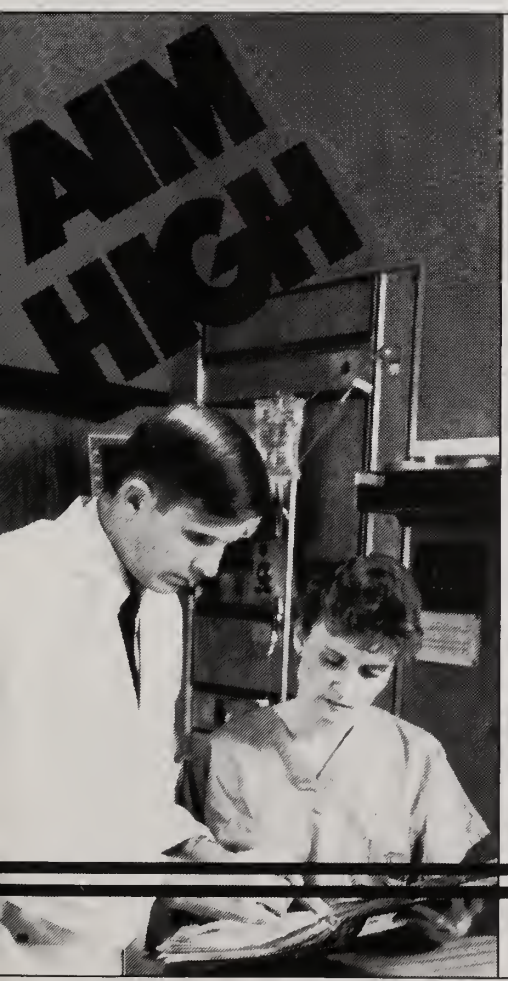
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Style

All manuscripts should adhere to the style adopted by the American Medical Association as illustrated in *JAMA* and detailed in the AMA's *Manual of Style*. An abstract of 150 words or less should accompany each paper and should state the exact question considered, the key points of methodology and success of execution, the key findings, and the conclusions directly supported by these findings. Footnotes, bibliographies, and legends for illustrations should be on separate sheets. References are to be listed in the order of their appearance in the article.

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THE LAST WORD

■ **Applications for OSMA Life Membership have** been approved for Eugene S. Cohen, MD, Robert D. Grubb, MD, Leon Horowitz, MD, Robert A. Jordan, MD, Ralph S. McCants, MD, and Gisela K. Schuller, MD, Tulsa; Burdge F. Green, MD, Stilwell; and Kenneth G. Ogg, MD, R. Alvin Rix, Jr., MD, and Richard G. Shrifrin, MD, Oklahoma City. The applications were approved by the OSMA Board of Trustees at its November 14 meeting in Oklahoma City.

■ **OSMA dues statements were mailed a few weeks** ago. Members are reminded that payment must be received by the OSMA no later than March 31, 1994.

■ **February 1, 1994, is the deadline for nomina**tions for the Ayerst Wyeth Physician Award for Community Service and the Donald J. Blair Friend of Medicine Award. The service award goes to a physician who, in addition to his or her medical practice, has contributed significantly to the community. The Blair award, formerly the Layman of the Year Award, is presented to a non-physician for his or her support of the science and art of medicine in Oklahoma. Winners are selected by the OSMA Board of Trustees at their February meeting each year and the awards are presented at the OSMA's Annual Meeting. Nominations, with supporting material, should be sent to Douglas C. Hubner, MD, Chairman, OSMA Board of Trustees, 601 Northwest Expressway, Oklahoma City, OK 73118.

■ **Oklahoma City internist Thomas N. Lynn, Jr.,** MD, has been named chairman of the OSMA Council on Continuing Medical Education. Dr. Lynn, a past chairman of the OSMA Board of Trustees, succeeds Dr. Lofty Basta.

■ **The OSMA's 1994 Directory is scheduled for dis**tribution this month. The directory, almost 200 pages, features easier-to-use page indexing and a new listing of physicians fluent in a foreign language. In the main physician roster, specialties and schools of graduation are spelled out, eliminating the cryptic codes formerly used. The listings of hospitals and physicians by city have been retained.

Every OSMA member will receive one directory at no charge, with additional directories available at $25 each. Non-members may purchase directories for $50 each. Bulk orders of ten or more are available at $25 per copy. Directories may be obtained by writing the OSMA, 601 Northwest Expressway, Oklahoma City, OK 73118, or by calling (405) 843-9571 or 1-800-522-9453. Checks should be made payable to the Oklahoma State Medical Association.

■ **The Oklahoma County Medical Society (OCMS),** in conjunction with Deaconess Hospital, has opened a free clinic for the indigent. Open Thursday evenings, the clinic will be staffed by volunteer primary care physicians. Among those present at the ribbon cutting ceremony were Raymond L. Cornelison, Jr., MD, chairman of the OCMS Access to Care Committee; Roland A. Walters, MD, OCMS president; and Harold A. Masters, MD, medical director at Deaconess. The first physician volunteer for the clinic was Dr. Mukesh Parekh. Plans call for a second clinic to be opened in south Oklahoma City in conjunction with Southwest Medical Center of Oklahoma.

■ **The 1994 *Directory of Prescription Drug Indi**gent Programs* is now available to physicians. It lists 63 different pharmaceutical company programs that make prescription drugs available free of charge to physicians whose patients might not otherwise have access to necessary medications. Published by the Pharmaceutical Manufacturers Association, the directory lists each program, the company providing it, information on how to make a request for assistance, the prescription drugs covered, and basic eligibility criteria. Copies of the directory are available by writing to Directory of Pharmaceutical Indigent Programs, Pharmaceutical Manufacturers Association, 1100 15th Street, N.W., Washington, D.C. 20005.

■ **Copies of President Clinton's Health Security** Plan are on sale at the main bookstore of the U.S. Government Printing Office in Washington, D.C., and will soon be available at USGPO bookstores across the country. The 1,342-page book sells for $45 a copy; it is some four inches thick and weighs approximately six pounds. Copies may be ordered by calling (202) 783-3238, using Master Card or Visa. Delivery by Federal Express is an additional $8.50. An electronic copy of the legislation is available for downloading from the Electronic Network. See Bulletin #890 for details.

4795 356

Reference: 1. Jones PH, et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. *Clin Cardiol.* 1991;14:146-151.

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WARNINGS

Liver Enzymes: HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. Increases of serum transaminase (ALT, AST) values to more than 3 times the upper limit of normal occurring on 2 or more (not necessarily sequential) occasions have been reported in 1.3% of patients treated with pravastatin in the U.S. over an average period of 18 months. These abnormalities were not associated with cholestasis and did not appear to be related to treatment duration. In those patients in whom these abnormalities were believed to be related to pravastatin and who were discontinued from therapy, the transaminase levels usually fell slowly to pretreatment levels. These biochemical findings are usually asymptomatic although worldwide experience indicates that anorexia, weakness, and/or abdominal pain may also be present in rare patients.

As with other lipid-lowering agents, liver function tests should be performed during therapy with pravastatin. Serum aminotransferases, including ALT (SGPT), should be monitored before treatment begins, every six weeks for the first three months, every eight weeks during the remainder of the first year, and periodically thereafter (e.g., at about six-month intervals). Special attention should be given to patients who develop increased transaminase levels. Liver function tests should be repeated to confirm an elevation and subsequently monitored at more frequent intervals. If increases in AST and ALT equal or exceed three times the upper limit of normal and persist, then therapy should be discontinued. Persistence of significant aminotransferase elevations following discontinuation of therapy may warrant consideration of liver biopsy.

Active liver disease or unexplained transaminase elevations are contraindications to the use of pravastatin (see CONTRAINDICATIONS). Caution should be exercised when pravastatin is administered to patients with a history of liver disease or heavy alcohol ingestion (see CLINICAL PHARMACOLOGY: Pharmacokinetics/Metabolism). Such patients should be closely monitored, started at the lower end of the recommended dosing range, and titrated to the desired therapeutic effect.

Skeletal Muscle: Rhabdomyolysis with renal dysfunction secondary to myoglobinuria has been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients (see ADVERSE REACTIONS). Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values to greater than 10 times the upper limit of normal was reported to be possibly due to pravastatin in only one patient in clinical trials (<0.1%). Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK. Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. **Pravastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected. Pravastatin therapy should also be temporarily withheld in any patient experiencing an acute or serious condition predisposing to the development of renal failure secondary to rhabdomyolysis, e.g., sepsis; hypotension; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy.**

The risk of myopathy during treatment with lovastatin is increased if therapy with either cyclosporine, gemfibrozil, erythromycin, or niacin is administered concurrently. There is no experience with the use of pravastatin together with cyclosporine. Myopathy has not been observed in clinical trials involving small numbers of patients who were treated with pravastatin together with niacin. One trial of limited size involving combined therapy with pravastatin and gemfibrozil showed a trend toward more frequent CPK elevations and patient withdrawals due to musculoskeletal symptoms in the group receiving combined treatment as compared with the groups receiving placebo, gemfibrozil, or pravastatin monotherapy. Myopathy was not reported in this trial (see PRECAUTIONS: Drug Interactions). One patient developed myopathy when clofibrate was added to a previously well tolerated regimen of pravastatin; the myopathy resolved when clofibrate therapy was stopped and pravastatin treatment continued. **The use of fibrates alone may occasionally be associated with myopathy. The combined use of pravastatin and fibrates should generally be avoided.**

PRECAUTIONS

General: Pravastatin may elevate creatine phosphokinase and transaminase levels (see ADVERSE REACTIONS). This should be considered in the differential diagnosis of chest pain in a patient on therapy with pravastatin.

Homozygous Familial Hypercholesterolemia. Pravastatin has not been evaluated in patients with rare homozygous familial hypercholesterolemia. In this group of patients, it has been reported that HMG-CoA reductase inhibitors are less effective because the patients lack functional LDL receptors.

Renal Insufficiency. A single 20 mg oral dose of pravastatin was administered to 24 patients with varying degrees of renal impairment (as determined by creatinine clearance). No effect was observed on the pharmacokinetics of pravastatin or its 3α-hydroxy isomeric metabolite (SO 31,906). A small increase was seen in mean AUC values and half-life ($t_{1/2}$) for the inactive enzymatic ring hydroxylation metabolite (SO 31,945). Given this small sample size, the dosage administered, and the degree of individual variability, patients with renal impairment who are receiving pravastatin should be closely monitored.

Information for Patients: Patients should be advised to report promptly unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Drug Interactions: *Immunosuppressive Drugs, Gemfibrozil, Niacin (Nicotinic Acid), Erythromycin:* See WARNINGS: Skeletal Muscle.

Antipyrine: Clearance by the cytochrome P450 system was unaltered by concomitant administration of pravastatin. Since pravastatin does not appear to induce hepatic drug-metabolizing enzymes, it is not expected that any significant interaction of pravastatin with other drugs (e.g., phenytoin, quinidine) metabolized by the cytochrome P450 system will occur.

Cholestyramine/Colestipol: Concomitant administration resulted in an approximately 40 to 50% decrease in the mean AUC of pravastatin. However, when pravastatin was administered 1 hour before or 4 hours after cholestyramine or 1 hour before colestipol and a standard meal, there was no clinically significant decrease in bioavailability or therapeutic effect. (See DOSAGE AND ADMINISTRATION: Concomitant Therapy.)

Warfarin: In a study involving 10 healthy male subjects given pravastatin and warfarin concomitantly for 6 days, bioavailability parameters at steady state for pravastatin (parent compound) were not altered. Pravastatin did not alter the plasma protein-binding of warfarin. Concomitant dosing did increase the AUC and Cmax of warfarin but did not produce any changes in its anticoagulant action (i.e., no increase was seen in mean prothrombin time after 6 days of concomitant therapy). However, bleeding and extreme prolongation of prothrombin time has been reported with another drug in this class. Patients receiving warfarin-type anticoagulants should have their prothrombin times closely monitored when pravastatin is initiated or the dosage of pravastatin is changed.

Cimetidine: The $AUC_{0\text{-}12hr}$ for pravastatin when given with cimetidine was not significantly different from the AUC for pravastatin when given alone. A significant difference was observed between the AUC's for pravastatin when given with cimetidine compared to when administered with antacid.

Digoxin: In a crossover trial involving 18 healthy male subjects given pravastatin and digoxin concurrently for 9 days, the bioavailability parameters of digoxin were not affected. The AUC of pravastatin tended to increase, but the overall bioavailability of pravastatin plus its metabolites SO 31,906 and SO 31,945 was not altered.

Gemfibrozil: In a crossover study in 20 healthy male volunteers given concomitant single doses of pravastatin and gemfibrozil, there was a significant decrease in urinary excretion and protein binding of pravastatin. In addition, there was a significant increase in AUC, Cmax, and Tmax for the pravastatin metabolite SO 31,906. Combination therapy with pravastatin and gemfibrozil is generally not recommended.

In interaction studies with *aspirin, antacids* [1 hour prior to PRAVACHOL (pravastatin sodium)], *cimetidine, nicotinic acid,* or *probucol,* no statistically significant differences in bioavailability were seen when PRAVACHOL was administered.

Other Drugs: During clinical trials, no noticeable drug interactions were reported when PRAVACHOL was added to: diuretics, antihypertensives, digitalis, converting-enzyme inhibitors, calcium channel blockers, beta-blockers, or nitroglycerin.

Endocrine Function: HMG-CoA reductase inhibitors interfere with cholesterol synthesis and lower circulating cholesterol levels and, as such, might theoretically blunt adrenal or gonadal steroid hormone production. Results of clinical trials with pravastatin in males and post-menopausal females were inconsistent with regard to possible effects of the drug on basal steroid hormone levels. In a study of 21 males, the mean testosterone response to human chorionic gonadotropin was significantly reduced ($p<0.004$) after 16 weeks of treatment with 40 mg of pravastatin. However, the percentage of patients showing a ≥50% rise in plasma testosterone after human chorionic gonadotropin stimulation did not change significantly after therapy in these patients. The effects of HMG-CoA reductase inhibitors on spermatogenesis and fertility have not been studied in adequate numbers of patients. The effects, if any, of pravastatin on the pituitary-gonadal axis in pre-menopausal females are unknown. Patients treated with pravastatin who display clinical evidence of endocrine dysfunction should be evaluated appropriately. Caution should also be exercised if an HMG-CoA reductase inhibitor or other agent used to lower cholesterol levels is administered to patients also receiving other drugs (e.g., ketoconazole, spironolactone, cimetidine) that may diminish the levels or activity of steroid hormones.

CNS Toxicity: CNS vascular lesions, characterized by perivascular hemorrhage and edema and mononuclear cell infiltration of perivascular spaces, were seen in dogs treated with pravastatin at a dose of 25 mg/kg/day, a dose that produced a plasma drug level about 50 times higher than the mean drug level in humans taking 40 mg/day. Similar CNS vascular lesions have been observed with several other drugs in this class.

A chemically similar drug in this class produced optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in clinically normal dogs in a dose-dependent fashion starting at 60 mg/kg/day, a dose that produced mean plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose (as measured by total enzyme inhibitory activity). This same drug also produced vestibulocochlear Wallerian-like degeneration and retinal ganglion cell chromatolysis in dogs treated for 14 weeks at 180 mg/kg/day, a dose which resulted in a mean plasma drug level similar to that seen with the 60 mg/kg dose.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a 2-year study in rats fed pravastatin at doses of 10, 30, or 100 mg/kg body weight, there was an increased incidence of hepatocellular carcinomas in males at the highest dose ($p<0.01$). Although rats were given up to 125 times the human dose (HD) on a mg/kg body weight basis, their serum drug levels were only 6 to 10 times higher than those measured in humans given 40 mg pravastatin as measured by AUC.

The oral administration of 10, 30, or 100 mg/kg (producing plasma drug levels approximately 0.5 to 5.0 times human drug levels at 40 mg) of pravastatin to mice for 22 months resulted in a statistically significant increase in the incidence of malignant lymphomas in treated females when all treatment groups were pooled and compared to controls ($p<0.05$). The incidence was not dose-related and male mice were not affected.

A chemically similar drug in this class was administered to mice for 72 weeks at 25, 100, and 400 mg/kg body weight, which resulted in mean serum drug levels approximately 3, 15, and 33 times higher than the mean human serum drug concentration (as total inhibitory activity) after a 40 mg oral dose. Liver carcinomas were significantly increased in high-dose females and mid- and high-dose males, with a maximum incidence of 90 percent in males. The incidence of adenomas of the liver was significantly increased in mid- and high-dose females. Drug treatment also significantly increased the incidence of lung adenomas in mid- and high-dose males and females. Adenomas of the eye Harderian gland (a gland of the eye of rodents) were significantly higher in high-dose mice than in controls.

No evidence of mutagenicity was observed *in vitro,* with or without rat-liver metabolic activation, in the following studies: microbial mutagen tests, using mutant strains of *Salmonella typhimurium* or *Escherichia coli;* a forward mutation assay in L5178Y TK +/− mouse lymphoma cells; a chromosomal aberration test in hamster cells; and a gene conversion assay using *Saccharomyces cerevisiae.* In addition, there was no evidence of mutagenicity in either a dominant lethal test in mice or a micronucleus test in mice.

In a study in rats, with daily doses up to 500 mg/kg, pravastatin did not produce any adverse effects on fertility or general reproductive performance. However, in a study with another HMG-CoA reductase inhibitor, there was decreased fertility in male rats treated for 34 weeks at 25 mg/kg body weight, although this effect was not observed in a subsequent fertility study when this same dose was administered for 11 weeks (the entire cycle of spermatogenesis, including epididymal maturation). In rats treated with this same reductase inhibitor at 180 mg/kg/day, seminiferous tubule degeneration (necrosis and loss of spermatogenic epithelium) was observed. Although not seen with pravastatin, two similar drugs in this class caused drug-related testicular atrophy, decreased spermatogenesis, spermatocytic degeneration, and giant cell formation in dogs. The clinical significance of these findings is unclear.

Pregnancy: Pregnancy Category X: See CONTRAINDICATIONS.

Safety in pregnant women has not been established. Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 20x (rabbit) or 240x (rat) the human exposure based on surface area (mg/meter^2). However, in studies with another HMG-CoA reductase inhibitor, skeletal malformations were observed in rats and mice. PRAVACHOL (pravastatin sodium) should be administered to women of child-bearing potential only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the woman becomes pregnant while taking PRAVACHOL, it should be discontinued and the patient advised again as to the potential hazards to the fetus.

Nursing Mothers: A small amount of pravastatin is excreted in human breast milk. Because of the potential for serious adverse reactions in nursing infants, women taking PRAVACHOL should not nurse (see CONTRAINDICATIONS).

Pediatric Use: Safety and effectiveness in individuals less than 18 years old have not been established. Hence, treatment in patients less than 18 years old is not recommended at this time. (See also PRECAUTIONS: **General**.)

ADVERSE REACTIONS

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient. In 4-month long placebo-controlled trials, 1.7% of pravastatin-treated patients and 1.2% of placebo-treated patients were discontinued from treatment because of adverse experiences attributed to study drug therapy; this difference was not statistically significant. In long-term studies, the most common reasons for discontinuation were asymptomatic serum transaminase increases and mild, non-specific gastrointestinal complaints. During clinical trials the overall incidence of adverse events in the elderly was not different from the incidence observed in younger patients.

Adverse Clinical Events: All adverse clinical events (regardless of attribution) reported in more than 2% of pravastatin-treated patients in the placebo-controlled trials are identified in the table below; also shown are the percentages of patients in whom these medical events were believed to be related or possibly related to the drug.

	All Events %		Events Attributed to Study Drug %	
Body System/Event	Pravastatin (N = 900)	Placebo (N = 411)	Pravastatin (N = 900)	Placebo (N = 411)
Cardiovascular				
Cardiac Chest Pain	4.0	3.4	0.1	0.0
Dermatologic				
Rash	4.0*	1.1	1.3	0.9
Gastrointestinal				
Nausea/Vomiting	7.3	7.1	2.9	3.4
Diarrhea	6.2	5.6	2.0	1.9
Abdominal Pain	5.4	6.9	2.0	3.9
Constipation	4.0	7.1	2.4	5.1
Flatulence	3.3	3.6	2.7	3.4
Heartburn	2.9	1.9	2.0	0.7
General				
Fatigue	3.8	3.4	1.9	1.0
Chest Pain	3.7	1.9	0.3	0.2
Influenza	2.4*	0.7	0.0	0.0
Musculoskeletal				
Localized Pain	10.0	9.0	1.4	1.5
Myalgia	2.7	1.0	0.6	0.0
Nervous System				
Headache	6.2	3.9	1.7*	0.2
Dizziness	3.3	3.2	1.0	0.5
Renal/Genitourinary				
Urinary Abnormality	2.4	2.9	0.7	1.2
Respiratory				
Common Cold	7.0	6.3	0.0	0.0
Rhinitis	4.0	4.1	0.1	0.0
Cough	2.6	1.7	0.1	0.0

*Statistically significantly different from placebo.

The following effects have been reported with drugs in this class:

Skeletal: myopathy, rhabdomyolysis.

Neurological: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematous-like syndrome, polymyalgia rheumatica, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal: pancreatitis, hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma, anorexia, vomiting.

Reproductive: gynecomastia, loss of libido, erectile dysfunction.

Eye: progression of cataracts (lens opacities), ophthalmoplegia.

Laboratory Test Abnormalities: Increases in serum transaminase (ALT, AST) values and CPK have been observed (see WARNINGS).

Transient, asymptomatic eosinophilia has been reported. Eosinophil counts usually returned to normal despite continued therapy. Anemia, thrombocytopenia, and leukopenia have been reported with other HMG-CoA reductase inhibitors.

Concomitant Therapy: Pravastatin has been administered concurrently with cholestyramine, colestipol, nicotinic acid, probucol and gemfibrozil. Preliminary data suggest that the addition of either probucol or gemfibrozil to therapy with lovastatin or pravastatin is **not** associated with greater reduction in LDL-cholesterol than that achieved with lovastatin or pravastatin alone. No adverse reactions unique to the combination or in addition to those previously reported for each drug alone have been reported. Myopathy and rhabdomyolysis (with or without acute renal failure) have been reported when another HMG-CoA reductase inhibitor was used in combination with immunosuppressive drugs, gemfibrozil, erythromycin, or lipid-lowering doses of nicotinic acid. Concomitant therapy with HMG-CoA reductase inhibitors and these agents is generally not recommended. (See WARNINGS: **Skeletal Muscle** and PRECAUTIONS: **Drug Interactions.**)

OVERDOSAGE

There have been no reports of overdoses with pravastatin.

Should an accidental overdose occur, treat symptomatically and institute supportive measures as required.

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THE PRAVACHOL® DIRECTION IN LIPID MANAGEMENT

Effective lipid management doesn't have to be tough



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- Easy for patients — once-daily dosing, well tolerated
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PRAVACHOL®

pravastatin sodium 20 mg tablets

PRAVACHOL is indicated as an adjunct to diet for the reduction of elevated total and LDL-cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb) when the response to diet alone has not been adequate.

Active liver disease or unexplained transaminase elevations, pregnancy and lactation are contraindications to the use of pravastatin sodium.

Please see CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS in the brief summary of prescribing information on the adjacent page.

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